Licence Application

Tracking Number:	MI-2023-LI-03211-1	Application Source:	AST
Status:	Under Review	Inspection File Numbers:	
Original, Tracking Number	MI-2019-LI-01002-1	File Numbers:	Site: PH19/50654 Lic & Cer: E19-518787 Inspection: PH23/20896 App. Review: E23-519954
Licence Version Number:	5		
Issue Date:	15/04/2020	Expiry Date:	31/12/2030
Last Renewal Date:	08/08/2022	Next Renewal Date:	01/10/2023
Conditions:	This licence does not authorise the manufacture of medicines listed for export that include substances at a leve only permitted in medicines contained within schedules 2, 3, 4 & 8 of the Poisons Standard.		

Client Details

Applicant

Applicant Name:	GMP Pharmaceuticals Pty Limited		
Client ID:	29989		
Address:	7-9 Amax Avenue		
Suburb:	GIRRAWEEN	State:	NSW
Post code:	2145	Country:	Australia

Manufacturer

Manufacturer Name:	GMP Pharmaceuticals Pty Limited	Client ID:	29989

Billing Address

Address:	7-9 Amax Avenue		
Suburb:	GIRRAWEEN	State:	NSW
Postcode:	2145	Country:	Australia

Primary Site

Activities to be undertaken at the licence site(s):	Medicine - API & Sunscreens
Is this application for the collection of fresh blood components?	No

Site

Street Address:	60 Huntingwood Drive		
Suburb:	HUNTINGWOOD	State:	NSW
Post Code:	2148	Country:	Australia
Contact Name:	s22 [redacted]	Phone:	s22 [redacted]
Email:			
Mobile:			
Person in charge of Quality			

Control: [redacted]1.Blank CV for submission.pdf

Person in charge of Production: s22 [redacted]

Authorised Person for Release: s22 [redacted]

No	Manufacturing Type	Sterility	Manufacturing Class	Dosage Form	Product Code	Manufacturing Step
1	Medicine manufacture	Non Sterile	Not Applicable	All Dosage Forms	Listed Therapeutic Good	Storage
2	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	All Dosage Forms	Listed Therapeutic Good	Testing
3	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Powders Group	Listed Therapeutic Good	Finished Product Manufacture
4	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Granules Group	Listed Therapeutic Good	Finished Product Manufacture
5	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Solid Unit Dosage Forms - Tablets	Listed Therapeutic Good	Finished Product Manufacture
6	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Capsule, hard	Listed Therapeutic Good	Finished Product Manufacture

Secondary Site

Supporting Documents

An electronic copy of your Site Master File, Quality Manual or Technical Master File MUST support this application or it will not be valid. However y
may also provide a hardcopy of the files if an electronic one is not available.

Electronic Document List

Paper Document List

No	Document Type	Description	Method	Date

Fees and Payment

Fees and Payment

Fees: AUD $820.00

Payment Type:

Reports

Report Requested

No.	Date Requested	Report Type	Date Sent

Report Received

No.	Date Received	Report Type

Australian Government
Department of Health
Therapeutic Goods Administration

Office of Manufacturing Quality

MQB Form

FORM 3.1.a	Application Receipt & Review Processing Record – Licence Applications		
Comes under	SOP 3.1 Receipt and Review of Manufacturer Licence and Certification Applications		
Process Owner	Director, Licensing & Certification	Authorised by	Quality Management
Date issued	12 September 2017	Version #	1.0

This form includes:

Section 1 - Application Receipt

1.1 Licence Applications – General Information			
Tracking No	**MI-2023-LI-03211-1**	**Licence (Original Tracking No in application)**	**MI-2019-LI-01002-1**
Manufacturer	**GMP Pharmaceuticals Pty Limited**		
Site Address	**60 Huntingwood Drive HUNTINGWOOD NSW 2148**		
Application Type	☐ New - Proceed using Section 1.2.1. ☐ Variation - Proceed using Section 1.2.2 ☒ **Re-inspection - Proceed using Section 1.2.3**		
Records Management	TRIM: Create Containers ☒ **Yes** ☐ N/A (Variations) MIS: Assign '*Assignment* 'task. Add 'Management Comment'. ☒ **Yes**		

1.2 Licence Applications – Receipting 1.2.1 For New Licence Applications	
Records Management	Record file numbers (PH, Licence/Certificate, Application Review & Inspection) to application in MIS. Save copy & supporting documents in TRIM: ☐ Yes
Supporting Documents	SMF, Nominee CV's & Manu Statement supplied and saved to TRIM ☐ Yes **OR** ARCBS application: Evidence provided? ☐ Yes
Statutory Declaration	Statutory Test Certificate processed & saved to TRIM: ☐ Yes ☐ N/A (e.g. ARCBS)
Ready for Inspection Date	
MIS WM Process	Complete Assignment Task and assign Application Review task: ☐ Yes

1.2.2 For Licence Variation Applications	
Variation Type	☐ Administrative Manufacturer Details Change ☐ Authorisation / Condition Change ☐ Nominee Change ☐ Other – Specify:
Supporting Documents and Records Management	TRIM Container ('Licence/Certification'): Create a subfolder for the application; Save the application copy, supporting documents and checklist in TRIM: ☐ Yes
Other Applications	Are there other applications for the site: ☐ Yes ☐ N/A If yes, Tracking Number: Record details of variation (If there are multiple variation applications, confirm the variation in combination with other applications).
MIS WM Process	Complete Assignment Task and assign Application Review task: ☐ Yes
Notification	Send email to Inspector ☐ Yes

1.2.3 For Licence Re-inspection Applications	
Records Management	Record file numbers (PH, Licence/Certificate, Application Review & Inspection) to application in MIS. Save copy & supporting documents in TRIM: ☒ **Yes** **Site: PH19/50654** **Lic & Cer: E19-518787** **Inspection: PH23/20896** **App. Review: E23-51995**
Other Applications	Are there other applications for the site: ☐ Yes ☒ **No** If yes, Tracking Number:
MIS WM Process	Complete Assignment Task and assign Application Review task: ☒ **Yes**

1.3 Complete Receipting	
Initials: s22	**Date: 21/03/2023**
E-sign Checklist in TRIM: ☒ **Yes**	

Section 2 – Application Review

2.1 Application Review - Licence Applications	
2.1.1 Application Review – Licence Applications (New)	
Review all other applications for the site	Review Outcome:
Review application and supporting evidences	Review Outcome:
Is Inspection required?	☐ Yes ☐ No ☐ N/A Audit type: Number of Auditors: Duration: Audit Qualification: Due Date:
Generate Audit in MIS	Audit No:
Notify OMQ Scheduling for Initial and high priority Inspections	☐ Yes ☐ No ☐ N/A
Once Review is completed, re-assign the Application Review task to 'ARIST - Reviewed'	☐Complete

2.1.2 Application Review –Licence Applications (Re-inspection)

Review all other applications for the site	**Review Outcome**: N/A other applications in the in-tray
Review Audit details	**Review Outcome**: Details in the application D23-5231485, current repository D23-5232113 and current licence D22-5761042 are correct. **Details of Previous inspection:** **Re-inspection date:** completed 13/5/2021 **Final decision:** First A2, low listed, recommended re-inspection frequency of 30 months **Auditor Qualification:** Medicinal Products - non-sterile listed, 1 inspector, scheduled for 4 days **Details of Current inspection:** **Re-inspection due date:** 10/11/23 **Final decision:** **Auditor Qualification:** Medicinal Products - non-sterile listed, 1 inspector, scheduled for 4 days – updated as per - D21-2640669 **Inspection Record form** - D21-2640669 Recommended audit parameters as per inspection record form of previous inspection indicate audit parameters of 1 inspector by 4 days, AST has been updated to reflect - 1 inspector by 4 days for upcoming audit as per - D21-2640669
Is any change to re-inspection required?	☐ Yes ☒ **No** **If yes, details:**
Notify OMQ Scheduling if high priority Inspections (e.g. lifting suspension inspection, etc)	☐ Yes ☒ **No**
Once Review is completed, re-assign the Application Review task to 'ARIST - Reviewed'	☒ **Complete**

2.2 Complete Review	
Initials: s22	**Date:** 22/03/2023
E-sign in TRIM: ☒ **Yes**	

Section 3 – Peer Review

Peer review is only intended to be used for training purposes, or for periodic peer review.

The Peer Reviewer is to complete this section after reviewing sections 1 and 2 and any relevant evidence in the TRIM folder. Comments should be included in the right hand column, as applicable and appropriate.

3.1 Peer Review		
Peer review Required? *(If Yes select the reason for peer review)*	☐ Yes ☐ No	Training ☐ Periodic Peer Review ☐
Correctly followed the review process according to SOP 3.1 and WI 3.1.1? *If NO, provide comment*	☐ Yes ☐ No	
Conclusions of the review are appropriate? (Refer to Section 2) *If NO, provide comment:*	☐ Yes ☐ No	

3.2 Complete Peer Review	
Name:	**Date**: Click here to enter a date.
e-sign in TRIM: ☐ Yes	

Version history

Version	Description of change	Author/s	Effective date
1.0	New document	s22 [redacted]	12 Sep 2017

Document Change Proposal

Proposed changes to this MQB QMS Document must be initiated through the following document change proposal form: D17-769023

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Manufacturing
Quality
Branch

MQB - Form

FORM 5.2.a	Inspection Record		
Comes Under	SOP 5.2 – Inspection Preparation and Planning		
Process Owner	Director, Inspections	Authorised by	Quality Manager
Date Issued	7 June 2024	Version #	3.3

Section 1 – Inspection Preparation

Lead Inspector to complete this section when preparing to conduct an inspection, following SOP 5.2 – "Inspection Preparation and Planning".

Parameter:	Entry:
MIS Tracking Number:	MI-2023-LI-03211-1
Manufacturer Name:	GMP Pharmaceuticals Pty Limited
Date(s) of Inspection:	3 – 4 April 2025
Inspection Type(s):	☒Medicines ☐APIs ☐Bloods ☐Cellular Therapies ☐Tissues ☐Veterinary ☐Gene Therapies ☐Other (specify): ☐Re-inspection ☐Initial ☐Reduced scope ☒Surveillance ☐Special (select): ☐Close-out ☐Compliance
Inspection Method:	☒On-site ☐Remote ☐Hybrid
Sterility Status:	☒Non-sterile ☐Sterile

Inspection Scope: (SOP 5.2 Appendix 2)	Full product manufacture of non-sterile listed medicines in the form of tablets, hard capsules, powders and granules. Packaging, labelling & RFS of listed medicine soft gel capsules Storage of all non-sterile listed medicines dosage forms Testing of all non-sterile listed medicines dosage forms The inspection is a surveillance inspection with **reduced scope**, as detailed in the inspection plan (and outlined below in red)
2 items from each of the 5 streams	☐Stream 1 – Materials Control Warehousing ❒ GMP Contract agreements ❒ Control of storage areas ❒ Rejects Control ❒ Cleaning/Housekeeping ❒ Temperature/humidity monitoring ❒ Raw Materials/Bulk Materials ❒ Finished Goods ❒ Supplier Evaluation/API Audits ❒ Inventory Management System ❒ Returned goods ❒ Retention/Reference Samples ❒ Status Control-Identification/Traceability ❒ Waste Disposal ❒ Dispatch/Handling/Traceability Starting Materials ❒Receipt, Quarantine/Inspection/Testing ❒Control of utensils ❒Approval for use ❒Picking/Dispensing ❒Control of pre-printed packaging packaging/components ❒ Sampling area/Plans ❒ Retention Samples ❒ Cleaning/Housekeeping ❒ Control of Components ❒ Sampling/Approval of

☐ Stream 2 – Production System

Dispensing Areas

- ❒ Materials Flow
- ❒ Room grading
- ❒ Control of utensils
- ❒ Cleaning/Housekeeping
- ❒ Gowning/Access
- ❒ Equipment logs
- ❒ Retention Samples
- ❒ Containment

Production - Formulation Areas

- ❒ Materials Flow
- ❒ Room grading
- ❒ Water supply
- ❒ Preparation of solutions
- ❒ Solution Filtration
- ❒ IPQC testing
- ❒ Transfer of Bulk solutions to filling
- ❒ Gowning/Access
- ❒ Equipment logs
- ❒ Equipment CIP/SIP
- ❒ Mixing/Blending
- ❒ Bulk storage/monitoring
- ❒ Environmental Monitoring
- ❒ Batch record formats/entries

Production - Manufacture/Filling

- ❒ Process flow
- ❒ Batch record formats/entries
- ❒ Temp/Humidity/Pressure differentials
- ❒ Area condition/finishes
- ❒ Equipment CIP/SIP
- ❒ Dress codes/gowning/personal hygiene
- ❒ Cleaning procedures/records
- ❒ Contamination control – air/layout

- ❒ In-process checks/sampling
- ❒ Management of components

General

- ❒ Waste control
- ❒ Reconciliation
- ❒ Sampling plans (chem/micro)
- ❒ Line clearance
- ❒ Contamination control – air/layout

Production – Labelling/ Packaging

- ❒ Process flow
- ❒ Batch record formats/entries
- ❒ Temp/Humidity/Pressure differentials
- ❒ Area condition/finishes
- ❒ Labelling/Coding
- ❒ Reconciliation of components
- ❒ Check weighers/VISY
- ❒ Return of unused components
- ❒ Dress codes/gowning /personal hygiene
- ❒ Cleaning procedures/records
- ❒ Room grading
- ❒ Packaging Equipment
- ❒ IPQC checks & records
- ❒ Line clearance
- ❒ Rejected units
- ❒ Batch & Product displayed

IPC Laboratory

- ❒ Equipment calibrated/maintained
- ❒ Completion of Batch records
- ❒ Procedures/Records
- ❒ Cleaning procedures/records

☐ Stream 3 – Validation/ Qualification

- ❒ VMP (Schedule)
- ❒ Equipment List
- ❒ Document formats
- ❒ Equipment Qualification
- ❒ Revalidation

- ❒ Process validation and ongoing process verification
- ❒ Cleaning Validation/HBEL
- ❒ Computerised systems
- ❒ Temperature controlled areas

☐ Stream 4 – Facilities & Equipment

Review of Utilities & Services

❒ Preventive Maintenance ❒ Calibration
❒ Pest Control ❒ Waste Disposal

HVAC

❒ Area Classifications ❒ P&ID's
❒ Specifications/Design/Construction ❒ Filtration supply/return/exhaust
❒ Pressures/Containment strategy ❒ Room certification/airflow visualisation
❒ Monitoring/Control/Testing/Trends ❒ Handling of alarms and trending
❒ Operation/Checks/Cleaning ❒ Validation system/BMS/Alarms
❒ Power failure ❒ Equipment calibration and maintenance
❒ Environmental Monitoring

Water Systems

❒ Use / SOPs ❒ P&ID's
❒ Specifications/Design/Construction ❒ Sanitisation
❒ Monitoring/Control/Testing/Trends ❒ Operation/Checks/Cleaning
❒ Validation ❒ Equipment calibration and maintenance

Critical Production Equipment

❒ Use / SOPs ❒ P&ID's
❒ Specifications/Design/Construction ❒ Sterilisation/Sanitisation
❒ Monitoring/Control/Testing ❒ Operation/Checks/Cleaning
❒ Validation ❒ Equipment calibration and maintenance

Compressed air/gasses/vacuum (Natural Gas/O_2/N_2)

❒ Use / SOPs ❒ P&ID's
❒ Specifications/Design/Construction ❒ Sterilisation/Sanitisation
❒ Monitoring/Control/Testing ❒ Operation/Checks/Cleaning

❒ Validation ❒ Equipment calibration and maintenance

☐ Stream 5 – Quality Control

Chemistry

❒ Sample Preparation/Dispatch ❒ Stability
❒ Specifications and test methods
❒ Testing as per specification ❒ Test results (raw data)
❒ Method validation ❒ Reference standards
❒ Reagents/Volumetric Solutions ❒ Reference/retention samples
❒ Instruments/Equipment ❒ Equipment calibration/maintenance
❒ Equipment Qualification ❒ System suitability
❒ Water testing ❒ Personnel training
❒ Contract testing ❒ OOS/OOT Procedures
❒ Certificates of Analysis ❒ Release of results
❒ Data Management

Microbiology

❒ Sample Preparation/Dispatch ❒ Media Preparation/QC
❒ Culture collection ❒ Incubator monitoring/mapping
❒ Equipment Qualification ❒ Equipment calibration/maintenance
❒ Specifications
❒ Test methods ❒ Method validation
❒ Test results (raw data/computerised systems)
❒ OOS/OOT Procedures
❒ Water testing ❒ EM/PM (viable/non-viable)
❒ Antibiotic assays
❒ Data management
❒ Sample Preparation/Dispatch
❒ Contract testing ❒ Personnel training
❒ Certificates of Analysis ❒ Release of results

Initial email contact and email notification followed up with Inspection Announcement letter	Name s22 [redacted] Date: 11/3/2025 ☒Manufacturer ☐ Sponsor
Inspection preparation conducted and recorded/filed in accordance with SOP 5.2?	☒Yes ☐No (explain)
MIS pre-inspection task completed (WI 5.2.2)	☒Yes ☐No (explain)
~~International Biological manufacturer?~~	~~☐Yes ☐N/A~~ ~~Pre-inspection hours:~~

Section 2 – Inspection Conduct/Outcome

Lead Inspector to complete this section after conducting an inspection, following SOP 5.3 – "Conducting an Inspection".

Parameter:	Entry:		
Date back in office after Inspection:	7/04/2025		
Access denied?	☒No ☐Yes (explain)		
Sampling process (WI 5.3.7) conducted?	☐ Yes ☒ No	TRIM ref #	n/a
Any areas not covered during the inspection?	☒ No ☐ Yes (explain)		
Previous inspection findings: reviewed?	☐Yes, no further issues ☐ No (explain)	☒Yes, repeat issues identified ☐N/A	
Recalls verified on site? (Form 5.1.1a):	☐Yes, no further issues ☐ No (explain)	☐Yes, issues identified ☒N/A	
Inspection conducted and recorded/filed in accordance with SOP 5.3/5.4:	☒ Yes ☐ No (explain)		
Conflict of interest: Financial or other interest in inspected company?	☒ No ☐ Yes (explain)	Were gift / meal / other hospitality / travel / entertainment, etc. provided?	☒ No ☐ Yes (explain)

Inspection outcome			
Provisional compliance rating	☐ 1st A1 rating ☐ 2nd consecutive repeat ☐ 3rd or subsequent repeat		
	☒ A2		
	☐ A3 ☐ Repeat A3		
	☐ Unacceptable		
Referred to Review Panel (SOP 5.5)	☒ No ☐ Yes	Date referred: TRIM review panel folder ref #	n/a
MIS [Audit Document] data completed (WI 5.3.8)?	☒ Yes ☐ No (explain)		
Date PIL submitted for review (WI 5.3.10):	11/04/2025		
LI comments:	☒ N/A		

Reinspection Details	
Risk Category:	☐ High ☐ Medium ☐ Low ☒ Listed
Months to next inspection:	~~(H/M/L) ☐ 12 ☐ 15 ☐ 18 ☐ 20 ☐ 24 ☐ 36~~ (Listed) ☐ 18 ☒ 30 ☐ 42 ☐ 48 Comment:
LI recommended next inspection:	Team composition: 1 inspector Duration: 4 days Reaudit raised by LI as above ~~Reduced scope inspection: ☐ Yes ☐ No If yes, what is recommended.~~ ~~For medicines:~~ ~~☐ Stream 1 Materials Control ☐ Stream 2 Production System ☐ Stream 3 Validation/ Qualification ☐ Stream 4 Facilities & Equipment ☐ Stream 5 Quality Control~~
Inspection Notes	
Record any notes relevant to the inspection that may be useful to subsequent inspections, e.g. site access, travel/transport, accommodation, isolated work, PPE/WHS concerns, language barriers, alerts etc.	☒ N/A

Section 3 – PIL Peer Review / Create re-inspection

Peer reviewer to complete this section after reviewing the PIL for compliance with WI 5.3.10 "Writing a Post-inspection Letter (PIL)" and creating a re-inspection following SOP WI 5.3.11 "Creating a re-audit in MIS".

Parameter:	Entry:
Reviewer name:	s22 [redacted]
All requirements of WI 5.3.10 met?	☒ Yes ☐ No (explain)
Any feedback on PIL to LI required?	☒ No ☐ Yes (explain)
Need to see the PIL again?	☒ No ☐ Yes (explain)
Provisional compliance rating:	☒ Agree ☐ Disagree (explain)
If disagree then changed to:	☐ N/A
Refer to Review Panel?	☒ No ☐ Yes (explain)
Reinspection raised (MIS) (WI 5.3.11):	☒ Yes ☐ No (explain) **Raised by LI**
Reviewer's comments:	☐ N/A Good PIL
Lead Inspector to complete MIS Audit [Inspection] task following PIL review (WI 5.3.8):	☒ Yes ☐ No (explain)

Section 4 – Inspection Close-out & Report

Parameter:	Entry:		
Date PIL sent to manufacturer:	**11/04/2025**		
Date APVMA report sent: (for inspections performed under the MRA provisions)	☒N/A		
Date close-out report sent to manufacturer (WI 5.4.7):	**30/5/2025**		
Inspection close-out conducted and recorded/filed in accordance with SOP 5.4 & WI 5.4.6:	☒ Yes ☐ No (explain)		
~~International Biological manufacturer?~~	~~☐Yes ☐N/A~~ ~~Post inspection hours:~~		
	~~Date:~~	~~Hours:~~	
Final compliance rating:	☒As provisional ☐changed to AX If rating was changed – confirm reinspection details changed Explanation:		
Based on manufacturers response, is the duration of the next inspection sufficient? (WI 5.4.6)	☒ Yes ☐ No (explain if any additional time added) ~~**Additional time added:**~~ ~~MIS re-inspection amended: ☐ Yes~~		
Licence/certification/ clearance processing initiated:	☐ Yes ☒ No (explain)		
MIS POST Audit [Inspection] task completed (WI 5.4.3):	☐ No ☒ Yes (explain)		
Peer notified to complete Audit Completion task in MIS (WI 5.4.4)	☒ Yes ☐ No	Name of peer notified:	s22 [redacted]
e-signed (PIL, REPORT, THIS FORM) in TRIM:	☒ Yes ☐ No		

From: s22 [redacted]
To:
Subject: TGA Inspection - GMP Pharmaceuticals Pty Limited - Huntingwood - April 2025 [SEC=OFFICIAL]
Date: Tuesday, 11 March 2025 5:35:06 PM
Attachments: TGA Inspection Announcement Letter - GMP Pharmaceuticals Pty Ltd - Huntingwood - April 2025.pdf
image001.png
image002.png
image003.png
image004.gif
image005.png

Dear s22 [redacted]

Please find attached the announcement letter for the upcoming TGA inspection of GMP Pharmaceuticals Pty Limited's Huntingwood facility.

The letter contains a request for information required prior to the inspection. I would appreciate it if you could supply the requested documents by 24th March.

I look forward to working with you again in a few weeks.

Regards
s22 [redacted]

s22 [redacted] (she/they)
Senior Inspector
Inspections and Compliance | Manufacturing Quality Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s22 [redacted] @health.gov.au
Location: Remote
Post: PO Box 100, Woden ACT 2606 Australia
www.tga.gov.au

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met

Australian Government
Department of Health
Therapeutic Goods Administration

s22
GMP Pharmaceuticals Pty Limited
60 Huntingwood Drive
Huntingwood
NSW 2148

Dear s22

Subject: Surveillance Inspection announcement

I am writing to confirm our telephone conversation to announce the TGA inspection that is to take place at your Huntingwood facility, on 3 – 4 April 2025, commencing at approximately 9.30 AM on the first day.

The purpose of the inspection is to establish compliance with the standard determined under the *Therapeutic Goods Act 1989*: the PIC/S Guide to Good Manufacturing Practice for medicinal products – PE 009-16, 1 February 2022.

Additional information on the inspection process is available in the document TGA Guidance on licensing / certification inspections, which can be accessed from the TGA web site at https://www.tga.gov.au/manufacturing-inspections.

On this occasion, the inspection team will consist of one inspector: s22

This inspection is now part of a firm schedule and will only be cancelled in exceptional circumstances.

To facilitate inspection preparation, would you kindly provide the following information no later than 24th March 2025:

- Current Site Master File and Quality Manual
- Master List/Register of SOPs used for therapeutic activities
- Any major changes since the last TGA inspection in May 2022, e.g. key personnel, equipment, materials/products handled on site.
- A list of medicinal products manufactured in the last 12 months.

Also note the following information:

- All correspondence relating the inspection will be performed using electronic documents only. Please provide any documents requested as electronic copies only.
- The TGA website includes information on the inspection procedures and reporting processes that will apply to this inspection. Please refer to the information available at: https://www.tga.gov.au/publication/australian-manufacturing-licences-and-overseas-gmp-certification

- As per Australian Government requirements, inspectors cannot accept any gifts in relation to the inspection.

The final compliance rating following this inspection will be determined after review of your response/s to the post inspection letter. Information on the TGA's system to determine manufacturer compliance can be found on the TGA web site at http://www.tga.gov.au/industry/manuf-compliance-history.htm. Once the inspection is closed out, a report will be sent to you to confirm close out, which will also advise on the final compliance rating. Subsequently, the compliance rating will be used as input to determine re-inspection frequency. Information on how this is done can be found on the TGA web site at http://www.tga.gov.au/industry/manuf-inspections-frequency.htm.

Should you have any questions regarding the inspection, please do not hesitate to contact me.

Yours sincerely

Signed and authorised by

s22
Senior Inspector
Manufacturing Quality Branch

Date: 11 March 2025

Level 12, 130 George Street
Parramatta 2150 NSW

Phone: s22
E-mail: s22 @health.gov.au

CHANGE CONTROL REQUEST FORM

CHANGE CONTROL NUMBER: (CC): 25040	Date & Signature (Document Control/Delegate): s22 [redacted] 20/03/2025	
CHANGE REQUESTED BY: s22 [redacted]	Signature: s22 [redacted] 20/03/2025	Position: QA Validation Engineer

1. **DETAILS OF CHANGE REQUESTED** (Provide a detailed description of the problem, circumstances leading to the requested change)

Site Master File (Document No.: SMF001) needs to be updated.

2. **REASON & JUSTIFICATION** (Describe the reason why the changes has been requested and the justification for request)

To update the organisational chart, key personnel and their qualifications accordingly.

3. **SUPPORTING INFORMATION** (Provide print out documents if applicable to the change)

4. **PRIORITY OF CHANGE** (Assessed by requestor & QA)

Low		High	✓

5. SCALE OF CHANGE (Assessed by requestor and QA)

Major		Minor	✓

6. RISK ASSESSMENT:

Based on scientific knowledge, evaluate the risk to the quality of the product using the following Risk Level Matrix

Risk Level Matrix: (Circle likelihood, severity, and risk level in the below table)

Likelihood (probability)	Severity (consequences)				
	1 Insignificant	2 Minor	3 Moderate	4 Major	5 Critical
5 Almost certain	Medium	Medium	High	Extreme	Extreme
4 Likely	Low	Medium	High	High	Extreme
3 Possible	Low	Medium	High	High	High
2 Unlikely	Low	Low	Medium	Medium	High
1 Rare	Low	Low	Low	Low	Medium

Where these have the following meanings and ratings:

Likelihood (probability) of the failure occurring is
- **Rare** could occur in very exceptional circumstances.
- **Unlikely** could occur at some time.
- **Possible** may occur at some time.
- **Likely** will probably occur at least once.
- **Almost certain** is expected to occur in most circumstances.

Severity (consequences) of the failure on the end user or the final product
- **Insignificant** no personal harm or no effect on product quality.
- **Minor** no personal harm or a minor effect on product quality.
- **Moderate** localized personal harm or does affect product quality.
- **Major** may cause illness to the end user or cause a rejection of a product.
- **Critical** potential life threatening to the end user.

Probability of Detection

Evaluate the probability of detection of the potential hazards by conducting a basic review of the existing quality system and processes at GMP. To do so, determine the overall 'frequency rating' based on likelihood of occurrence and likelihood of detection. This may include identifying and analyzing the people and processes that would ensure detection of the hazard. For example:
- In-process checks
- Quality controls analyses
- Standard Operating Procedures
- Detection by sponsors or costumers

Identify and justify the overall frequency rating in writing on the matrix below.

LIKELIHOOD OF OCCURRENCE	DETECTION	
	Unlikely to be Detected	Likely to be Detected
Likely to Occur	Frequent	Remote
Unlikely to Occur	Remote	Improbable

Evaluate the risks

Scale the Risk Level with the Probability of Detection to assess the final Risk Level. Discuss the finding and make the decisions to accept or to control the risk. Use the Risk Level Acceptance Criteria below to decide if the risk is acceptable or how to reduce the risk to the acceptable level.

Risk Acceptable Criteria

(Low)	Risk is Acceptable and documented
Medium	Risk needs to be investigated by the QA and Production Department.
High	General Manager needs to be informed.
Extreme	Risk is Unacceptable and significant changes required.

RISK ASSESSMENT REPORT (Risk Acceptable/Unacceptable)

Several key personnel and positions have recently changed at the GMP Pharmaceuticals Pty. Ltd. (Huntingwood site). However, the newly appointed individuals have prior experience working in Good Manufacturing Practice (GMP) facilities. Notably, they previously worked at the Girraween site of GMP Pharmaceuticals Pty Ltd. before joining to the Huntingwood site.

So, this change doesn't have any impact to maintain overall GMP in GMP Pharmaceuticals Pty. Ltd (Huntingwood site). The site master file (SMF) will be updated accordingly.

Based on the above assessment, the risk is low, and it is acceptable.

Assessed By: s22 [redacted] Sign/Date: s22 [redacted] 20/03/2025

7. APPROVED BY (the requestor must tick the appropriate department, or not applicable (NA) & signed/date for departments with no involvement in the proposed changes).

DEPARTMENT	REQ[D]	COMMENTS	INITIAL & DATE
MD			
Operation/Production			
Quality Assurance	✓	Approved	s22 [redacted] 20/03/25
Quality Control			
Micro Lab			
Validation			
Engineering			
Research & Development			
Sales & Marketing			
Warehouse			
Technical			
Purchasing			
Customer			
IT			
Other			

8. FINAL APPROVAL TO PROCEED WITH CHANGE

QA Manager or Delegate sign & date as FINAL approval to Proceed

COMMENTS:

Approved to proceed.

SIGN & DATE: s22 [redacted] 20/03/2025

9. FOLLOW-ON WORK REQUIRED *(This can be filled out by any one of the approval signatories or by the initiator)*

Actions	Tick (✓) if required	Actions	Tick (✓) if required
GMP Agreement		MWO	
SOP		PWO/Packing Instruction	
Forms		Artwork Approval by Client	
Food Safety and Quality Manual		Validation	
Raw Material Spec/Sample Result Sheet		Service Agreements	
Packing Component Spec/Sample Result Sheet		Training	
Supplier qualification		Stability Program	
BG Formulation/Specification		Equipment Calibration	
FP Specification		Other *(Please Specify)*	SMF

TASK LIST: Please write the detailed tasks for above actions

	Target date	Done by/date
To update the site master file (SMF) (DOC.NO.: SMF001) to V09.	20/04/2025	

10. VERIFICATION OF FOLLOW-ON WORK & CHANGE CONTROL CLOSE-OUT

(Provide evidence of completion and effectiveness of Follow-on Work, include document numbers, e-mails, training records etc. For any un-foreseen consequences or risks, please provide below.)

COMMENTS:

Verified by: _____ Date: _____

11. Final Approval

QA Manager or Delegate: _____ Date: _____

Register close out by: _____ Date: _____

12. Document History:

Ver no	Change Control #	Prepared by	Approved by	Brief Description of Changes	Date
1	NA	s22	s22	New Document	23/12/2020
2	CC21001			Add more details for section 5, 6 and 8.	05/01/2021
3	CC21030			Changed 'Priority of Change'. Added target date for task list. Addressed possible un-foreseen risks during verification. Added major/minor classification to changes.	30/06/2021
4	CC22007			Reviewed and confirmed up to date. Updated a description of RISK ASSESSMENT section.	14/02/2022
5	CC22027			Added 'Probability of Detection' section to Risk Assessment. Updated the 'Evaluate the Risks' section	28/07/2022

Master List

SOP Number	Title	Revision	Vault	Release Date	Effective Date	InfoCard Type	InfoCard Subtype
SOP PR0001	Occupational Health and Safety	2	HUN-ADMIN-Release	5/11/2021 0:00	5/11/2021 0:00	HUN-SOP	ADM
SOP PR0002	Sick Leave	2	HUN-ADMIN-Release	5/11/2021 0:00	5/11/2021 0:00	HUN-SOP	ADM
SOP PR0003	Emergency Evacuation Procedure	2	HUN-ADMIN-Release	5/11/2021 0:00	5/11/2021 0:00	HUN-SOP	ADM
SOP PR0004	Induction Training - New Employees	3	HUN-ADMIN-Release	5/11/2021 0:00	5/11/2021 0:00	HUN-SOP	ADM
SOP PR0005	First Aid	2	HUN-ADMIN-Release	5/11/2021 0:00	5/11/2021 0:00	HUN-SOP	ADM
SOP PR0006	Injury Management Procedure	2	HUN-ADMIN-Release	5/11/2021 0:00	5/11/2021 0:00	HUN-SOP	ADM
SOP PR0007	Personal Hygiene	3	HUN-ADMIN-Release	19/01/2023 0:00	19/01/2023 0:00	HUN-SOP	ADM
SOP PR0008	Harassment & Bullying Within Workplace	2	HUN-ADMIN-Release	5/11/2021 0:00	5/11/2021 0:00	HUN-SOP	ADM
SOP PR0009	Handling of Dangerous Goods	2	HUN-ADMIN-Release	5/11/2021 0:00	5/11/2021 0:00	HUN-SOP	ADM
SOP PR0010	Security and Removal of Company Property	2	HUN-ADMIN-Release	5/11/2021 0:00	5/11/2021 0:00	HUN-SOP	ADM
SOP PR0011	Wearing Jewellery and Cosmetics in Work Place	3	HUN-ADMIN-Release	19/01/2023 0:00	19/01/2023 0:00	HUN-SOP	ADM
SOP PR0012	Glass/brittle Material Breakage Policy	2	HUN-ADMIN-Release	18/03/2025 11:20	18/03/2025 11:20	HUN-SOP	ADM
SOP PR0013	Gowning Procedure	3	HUN-ADMIN-Release	8/04/2021 1:00	8/04/2021 1:00	HUN-SOP	ADM
SOP ENG0001	Preventative Maintenance Policy	2	HUN-ENG-Release	17/12/2021 0:00	17/12/2021 0:00	HUN-SOP	ENG
SOP ENG0002	Engineering Project Management	2	HUN-ENG-Release	17/12/2021 0:00	17/12/2021 0:00	HUN-SOP	ENG
SOP ENG0003	Contractor Management System	3	HUN-ENG-Release	31/01/2023 0:00	31/01/2023 0:00	HUN-SOP	ENG
SOP ENG0004	Machine transfer Between Non-Clean Room and Clean Room Area	1	HUN-ENG-Release	17/12/2021 0:00	17/12/2021 0:00	HUN-SOP	ENG
SOP ENG0005	Safe and Effective Operations of the Compressed Air	1	HUN-ENG-Release	17/12/2021 0:00	17/12/2021 0:00	HUN-SOP	ENG
SOP ENG0006	Lockout Tag Out (L.O.T.O) Procedure	1	HUN-ENG-Release	12/09/2022 1:00	12/09/2022 1:00	HUN-SOP	ENG
SOP ENG0007	Tooling Punch Inspection Kit	1	HUN-ENG-Release	3/04/2023 1:00	3/04/2023 1:00	HUN-SOP	ENG
SOP ENG0008	Tooling Punch Polishing Kit	1	HUN-ENG-Release	3/04/2023 1:00	3/04/2023 1:00	HUN-SOP	ENG
SOP ENG0009	MSOP for freezer	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0010	MSOP for vaccume freeze dryer	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0011	MSOP for cooking machine	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0012	MSOP for CIP tank	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0013	MSOP For Air compressor	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0014	MSOP For Aeration Machine	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0015	MSOP for DEPOSITOR machine	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0016	MSOP for AIR SHOWER	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0017	MSOP For water filter	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0018	MSOP for heat exchanger	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0020	MSOP for metal seperator	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0021	MSOP for sachet machine	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0022	MSOP for yamato checkweigher	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0023	MSOP for metal detector	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0025	MSOP for buffer tank	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0026	MSOP for cool room	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0027	MSOP for flow wrapper	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0028	MSOP for A & D Checkweigher	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0029	MSOP for Metal seperator 2	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0030	MSOP for 3M Adjustable Case Sealer	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0031	MSOP for Mobile CIP Machine	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0032	MSOP For Shield Allegro XRAY Machine	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0034	MSOP for labelling machine FD	2	HUN-ENG-Release	11/09/2023 1:00	11/09/2023 1:00	HUN-SOP	ENG
SOP ENG0037	MSOP for Milk Powder Filling Machine	2	HUN-ENG-Release	11/09/2023 1:00	11/09/2023 1:00	HUN-SOP	ENG
SOP ENG0040	MSOP for Labelling Machine	2	HUN-ENG-Release	11/09/2023 1:00	11/09/2023 1:00	HUN-SOP	ENG
SOP ENG0041	MSOP for Shield Solo Xray Machine	2	HUN-ENG-Release	11/09/2023 1:00	11/09/2023 1:00	HUN-SOP	ENG
SOP ENG0042	MSOP for Smart Induction Sealer	2	HUN-ENG-Release	11/09/2023 1:00	11/09/2023 1:00	HUN-SOP	ENG
SOP ENG0043	MSOP for Sifter Machine	2	HUN-ENG-Release	11/09/2023 1:00	11/09/2023 1:00	HUN-SOP	ENG
SOP ENG0044	MSOP for Powder Liquid mixer	2	HUN-ENG-Release	11/09/2023 1:00	11/09/2023 1:00	HUN-SOP	ENG
SOP ENG0045	MSOP for Videojet 1620 Inkjet Coder	2	HUN-ENG-Release	11/09/2023 1:00	11/09/2023 1:00	HUN-SOP	ENG
SOP ENG0046	MSOP for Dry Powder Blender	2	HUN-ENG-Release	11/09/2023 1:00	11/09/2023 1:00	HUN-SOP	ENG
SOP ENG0047	MSOP for Joyo Can Seamer	2	HUN-ENG-Release	11/09/2023 1:00	11/09/2023 1:00	HUN-SOP	ENG
SOP ENG0048	MSOP for Vacuum System for Powder Line	2	HUN-ENG-Release	11/09/2023 1:00	11/09/2023 1:00	HUN-SOP	ENG
SOP ENG0049	MSOP for Vacuum Conveyer FD	2	HUN-ENG-Release	11/09/2023 1:00	11/09/2023 1:00	HUN-SOP	ENG
SOP ENG0050	MSOP for Washing Machine FD	2	HUN-ENG-Release	11/09/2023 1:00	11/09/2023 1:00	HUN-SOP	ENG
SOP ENG0051	MSOP for IRE Mixer FD	2	HUN-ENG-Release	11/09/2023 1:00	11/09/2023 1:00	HUN-SOP	ENG
SOP ENG0052	MSOP for S-5010EU-BX Flow Wrapper	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0053	MSOP for Vacuum Freeze Dryer 2	2	HUN-ENG-Release	14/06/2024 1:00	14/06/2024 1:00	HUN-SOP	ENG
SOP ENG0053	MSOP for Vacuum Freeze Dryer 2	1	HUN-ENG-Release	6/11/2020 0:00	6/11/2020 0:00	HUN-SOP	ENG
SOP ENG0054	MSOP for Checkweigher 2	1	HUN-ENG-Release	16/12/2020 0:00	16/12/2020 0:00	HUN-SOP	ENG
SOP ENG0054	MSOP for Checkweigher 2	2	HUN-ENG-Release	14/06/2024 1:00	14/06/2024 1:00	HUN-SOP	ENG
SOP ENG0055	MSOP for Flow wrapper-3	1	HUN-ENG-Release	20/05/2022 1:00	20/05/2022 1:00	HUN-SOP	ENG

SOP ENG0056	MSOP for Vertical Sealing Machine	2	HUN-ENG-Release	14/06/2024 1:00	14/06/2024 1:00	HUN-SOP	ENG
SOP ENG0056	MSOP for Vertical Sealing Machine	1	HUN-ENG-Release	28/02/2023 0:00	28/02/2023 0:00	HUN-SOP	ENG
SOP ENG0057	MSOP for HVAC	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0058	MSOP for Water cooled chiller 1 and 2	2	HUN-ENG-Release	23/01/2023 0:00	23/01/2023 0:00	HUN-SOP	ENG
SOP ENG0059	MSOP for RO WATER SYSTEM	2	HUN-ENG-Release	17/01/2022 0:00	17/01/2022 0:00	HUN-SOP	ENG
SOP ENG0060	MSOP for Lab HVAC	2	HUN-ENG-Release	11/09/2023 1:00	11/09/2023 1:00	HUN-SOP	ENG
SOP ENG0061	MSOP for Sampling room HVAC	2	HUN-ENG-Release	11/09/2023 1:00	11/09/2023 1:00	HUN-SOP	ENG
SOP ENG0063	MSOP for Powder line HVAC	2	HUN-ENG-Release	11/09/2023 1:00	11/09/2023 1:00	HUN-SOP	ENG
SOP ENG0065	MSOP for Tablet Press	2	HUN-ENG-Release	13/12/2023 0:00	13/12/2023 0:00	HUN-SOP	ENG
SOP ENG0066	MSOP for Metal Detector	2	HUN-ENG-Release	13/12/2023 0:00	13/12/2023 0:00	HUN-SOP	ENG
SOP ENG0067	MSOP for tablet deduster	2	HUN-ENG-Release	13/12/2023 0:00	13/12/2023 0:00	HUN-SOP	ENG
SOP ENG0068	MSOP for Tablet Hardness Tester	2	HUN-ENG-Release	13/12/2023 0:00	13/12/2023 0:00	HUN-SOP	ENG
SOP ENG0069	MSOP for Friability Test Machine	2	HUN-ENG-Release	13/12/2023 0:00	13/12/2023 0:00	HUN-SOP	ENG
SOP ENG0070	MSOP for Disintegration Test Machine	2	HUN-ENG-Release	13/12/2023 0:00	13/12/2023 0:00	HUN-SOP	ENG
SOP ENG0071	MSOP for Weighing Balance	2	HUN-ENG-Release	11/09/2023 1:00	11/09/2023 1:00	HUN-SOP	ENG
SOP ENG0072	MSOP for Automatic Coating Machine	1	HUN-ENG-Release	6/01/2022 0:00	6/01/2022 0:00	HUN-SOP	ENG
SOP ENG0073	MSOP For Wet Granulation Machine - FBD	1	HUN-ENG-Release	23/02/2022 0:00	23/02/2022 0:00	HUN-SOP	ENG
SOP ENG0074	MSOP For Wet Granulation Machine - RMG	1	HUN-ENG-Release	23/02/2022 0:00	23/02/2022 0:00	HUN-SOP	ENG
SOP ENG0075	MSOP For Wet Granulation Machine - DCM	1	HUN-ENG-Release	23/02/2022 0:00	23/02/2022 0:00	HUN-SOP	ENG
SOP ENG0076	MSOP For Wet Granulation Machine - WIP	1	HUN-ENG-Release	23/02/2022 0:00	23/02/2022 0:00	HUN-SOP	ENG
SOP ENG0077	MSOP For Capsule Filling Machine	1	HUN-ENG-Release	22/03/2022 0:00	22/03/2022 0:00	HUN-SOP	ENG
SOP ENG0078	MSOP for YHA-Portable Blender	1	HUN-ENG-Release	1/06/2022 1:00	1/06/2022 1:00	HUN-SOP	ENG
SOP ENG0079	MSOP forPortable Liquid Mixer	1	HUN-ENG-Release	21/10/2022 0:00	21/10/2022 0:00	HUN-SOP	ENG
SOP ENG0080	MSOP forP130S Tablet Press Machine	1	HUN-ENG-Release	21/10/2022 0:00	21/10/2022 0:00	HUN-SOP	ENG
SOP ENG0081	MSOP forPG26 Rotary Tablet press machine	1	HUN-ENG-Release	29/03/2023 0:00	29/03/2023 0:00	HUN-SOP	ENG
SOP ENG0082	MSOP forTablet counting machine	1	HUN-ENG-Release	24/04/2023 1:00	24/04/2023 1:00	HUN-SOP	ENG
SOP ENG0083	MSOP for Semi -auto capping machine	1	HUN-ENG-Release	5/05/2023 1:00	5/05/2023 1:00	HUN-SOP	ENG
SOP ENG0084	MSOP for square bottle labelling machine	1	HUN-ENG-Release	3/07/2023 1:00	3/07/2023 1:00	HUN-SOP	ENG
SOP ENG0085	MSOP for high speed tablet counting machine	1	HUN-ENG-Release	28/07/2023 1:00	28/07/2023 1:00	HUN-SOP	ENG
SOP ENG0086	MSOP for Shark bottle capping machine	1	HUN-ENG-Release	29/09/2023 1:00	29/09/2023 1:00	HUN-SOP	ENG
SOP ENG0087	MSOP for BP600AR Shrink Wrapper	1	HUN-ENG-Release	1/11/2023 0:00	1/11/2023 0:00	HUN-SOP	ENG
SOP ENG0088	MSOP for 3M Case sealer Dry area	1	HUN-ENG-Release	14/11/2023 0:00	14/11/2023 0:00	HUN-SOP	ENG
SOP ENG0089	MSOP For Vacuum Conveyer Dry Area	1	HUN-ENG-Release	18/12/2023 0:00	18/12/2023 0:00	HUN-SOP	ENG
SOP ENG0090	MSOP for Tablet HVAC	1	HUN-ENG-Release	23/12/2020 0:00	23/12/2020 0:00	HUN-SOP	ENG
SOP ENG0091	MSOP for Steam Boiler	1	HUN-ENG-Release	14/06/2024 1:00	14/06/2024 1:00	HUN-SOP	ENG
SOP ENG0091	MSOP for Steam Boiler	2	HUN-ENG-Release	14/06/2024 1:00	14/06/2024 1:00	HUN-SOP	ENG
SOP ENG0092	MSOP FOR Tablet manufacturing facility	1	HUN-ENG-Release	19/11/2021 0:00	19/11/2021 0:00	HUN-SOP	ENG
SOP ENG0093	MSOP for Tablet Manufacturing HVAC	1	HUN-ENG-Release	24/11/2021 0:00	24/11/2021 0:00	HUN-SOP	ENG
SOP ENG0094	MSOP For Sachet Line HVAC	1	HUN-ENG-Release	26/07/2021 1:00	26/07/2021 1:00	HUN-SOP	ENG
SOP ENG0094	MSOP For Sachet Line HVAC	2	HUN-ENG-Release	4/07/2024 1:00	4/07/2024 1:00	HUN-SOP	ENG
SOP ENG0095	MSOP for Sachet Room Facilities	2	HUN-ENG-Release	4/07/2024 1:00	4/07/2024 1:00	HUN-SOP	ENG
SOP ENG0095	MSOP for Sachet Room Facilities	1	HUN-ENG-Release	28/07/2021 1:00	28/07/2021 1:00	HUN-SOP	ENG
SOP ENG0096	MSOP For Dust Collector	1	HUN-ENG-Release	22/06/2021 1:00	22/06/2021 1:00	HUN-SOP	ENG
SOP ENG0096	MSOP For Dust Collector	2	HUN-ENG-Release	17/06/2024 1:00	17/06/2024 1:00	HUN-SOP	ENG
SOP ENG0097	MSOP for Powder Can Facility	1	HUN-ENG-Release	19/11/2021 0:00	19/11/2021 0:00	HUN-SOP	ENG
SOP ENG0098	MSOP For Powder Can Packing HVAC	1	HUN-ENG-Release	24/11/2021 0:00	24/11/2021 0:00	HUN-SOP	ENG
SOP ENG0099	MSOP for Joyo Can Seamer 2	2	HUN-ENG-Release	13/12/2023 0:00	13/12/2023 0:00	HUN-SOP	ENG
SOP ENG0100	MSOP for YHA Blender	2	HUN-ENG-Release	13/12/2023 0:00	13/12/2023 0:00	HUN-SOP	ENG
SOP ENG0101	MSOP for Single Stick Machine	1	HUN-ENG-Release	3/05/2021 1:00	3/05/2021 1:00	HUN-SOP	ENG
SOP ENG0102	MSOP for Cellowrap Machine	2	HUN-ENG-Release	17/06/2024 1:00	17/06/2024 1:00	HUN-SOP	ENG
SOP ENG0102	MSOP for Cellowrap Machine	1	HUN-ENG-Release	21/06/2021 1:00	21/06/2021 1:00	HUN-SOP	ENG
SOP ENG0103	MSOP for Vibrating Sieve-1	2	HUN-ENG-Release	17/06/2024 1:00	17/06/2024 1:00	HUN-SOP	ENG
SOP ENG0103	MSOP for Vibrating Sieve-1	1	HUN-ENG-Release	24/06/2021 1:00	24/06/2021 1:00	HUN-SOP	ENG
SOP ENG0104	MSOP for Vibrating Sieve-2	2	HUN-ENG-Release	17/06/2024 1:00	17/06/2024 1:00	HUN-SOP	ENG
SOP ENG0104	MSOP for Vibrating Sieve-2	1	HUN-ENG-Release	24/06/2021 1:00	24/06/2021 1:00	HUN-SOP	ENG
SOP ENG0105	MSOP for 8 Lane sachet-1	1	HUN-ENG-Release	14/10/2021 0:00	14/10/2021 0:00	HUN-SOP	ENG
SOP ENG0106	MSOP for Anritsu XR75 Series X-Ray sachet-1	2	HUN-ENG-Release	4/07/2024 1:00	4/07/2024 1:00	HUN-SOP	ENG
SOP ENG0106	MSOP for Anritsu XR75 Series X-Ray sachet-1	1	HUN-ENG-Release	26/07/2021 1:00	26/07/2021 1:00	HUN-SOP	ENG
SOP ENG0107	MSOP for Baoli JB Series Milling Machine	1	HUN-ENG-Release	28/07/2021 1:00	28/07/2021 1:00	HUN-SOP	ENG
SOP ENG0107	MSOP for Baoli JB Series Milling Machine	2	HUN-ENG-Release	4/07/2024 1:00	4/07/2024 1:00	HUN-SOP	ENG
SOP ENG0108	MSOP for Jiangnan JFZ Grinding Machine	1	HUN-ENG-Release	28/07/2021 1:00	28/07/2021 1:00	HUN-SOP	ENG
SOP ENG0108	MSOP for Jiangnan JFZ Grinding Machine	2	HUN-ENG-Release	4/07/2024 1:00	4/07/2024 1:00	HUN-SOP	ENG
SOP ENG0110	MSOP for 12 Lane Sachet Machine-Automation	1	HUN-ENG-Release	21/09/2021 1:00	21/09/2021 1:00	HUN-SOP	ENG
SOP ENG0111	MSOP for Eiahe Pouch Machine	1	HUN-ENG-Release	14/10/2021 0:00	14/10/2021 0:00	HUN-SOP	ENG
SOP ENG0112	MSOP for 8 Lane sachet-1	1	HUN-ENG-Release	14/10/2021 0:00	14/10/2021 0:00	HUN-SOP	ENG

SOP ENG0113	MSOP For Mobile CIP Machine	1	HUN-ENG-Release	13/10/2022 0:00	13/10/2022 0:00	HUN-SOP	ENG
SOP ENG0114	MSOP For Fitzpatrick milling machine	1	HUN-ENG-Release	1/03/2023 0:00	1/03/2023 0:00	HUN-SOP	ENG
SOP ENG0115	MSOP For Shrink wrap machine	1	HUN-ENG-Release	1/03/2023 0:00	1/03/2023 0:00	HUN-SOP	ENG
SOP MIC0001	CLEANING AND MAINTENANCE OF THE MICROBIOLOGY LABORATORY	2	HUN-MIC-Release	25/08/2023 1:00	25/08/2023 1:00	HUN-SOP	MIC
SOP MIC0002	CLEANING AND CHEMICAL SPILLAGES IN THE MICROBIOLOGY LABORATORY	2	HUN-MIC-Release	28/11/2022 0:00	28/11/2022 0:00	HUN-SOP	MIC
SOP MIC0003	PERSONAL HEALTH HYGIENE AND SAFETY IN THE MICROBIOLOGY LABORATORY	3	HUN-MIC-Release	18/08/2023 1:00	18/08/2023 1:00	HUN-SOP	MIC
SOP MIC0004	OPERATION OF THE SAFETY SHOWER AND EYEWASH IN THE MICRO LAB	2	HUN-MIC-Release	19/11/2022 0:00	19/11/2022 0:00	HUN-SOP	MIC
SOP MIC0005	LONE WORKER ALARM	2	HUN-MIC-Release	16/01/2023 0:00	16/01/2023 0:00	HUN-SOP	MIC
SOP MIC0006	THE GRAM STAIN	2	HUN-MIC-Release	20/11/2022 0:00	20/11/2022 0:00	HUN-SOP	MIC
SOP MIC0007	QUALITY CONTROL REQUIREMENTS OF MICROBIOLOGICAL MEDIA, REAGENTS AND DILUENTS	3	HUN-MIC-Release	25/11/2021 0:00	25/11/2021 0:00	HUN-SOP	MIC
SOP MIC0008	DETERMINATION OF EXPIRY DATE FOR SOLID AND LIQUID MEDIA	2	HUN-MIC-Release	22/11/2022 0:00	22/11/2022 0:00	HUN-SOP	MIC
SOP MIC0009	ENUMERATION OF BILE TOLERANT GRAM NEGATIVE BACTERIA (BP)	2	HUN-MIC-Release	7/03/2025 14:51	7/03/2025 14:51	HUN-SOP	MIC
SOP MIC0010	DETERMINATION OF PRESENCE OR ABSENCE OF SALMONELLA SAPP	4	HUN-MIC-Release	7/03/2025 15:13	7/03/2025 15:13	HUN-SOP	MIC
SOP MIC0011	DETERMINATION OF PRESENCE OR ABSENCE OF E.COLI	3	HUN-MIC-Release	7/03/2025 15:23	7/03/2025 15:23	HUN-SOP	MIC
SOP MIC0012	OPERATION OF THE INTEGRA DOSE IT P910 PERISTALIC PUMP	2	HUN-MIC-Release	16/01/2024 0:00	16/01/2024 0:00	HUN-SOP	MIC
SOP MIC0013	IDENTIFICATIOPN OF MICROORGANISMS BY API KIT	2	HUN-MIC-Release	10/03/2023 0:00	10/03/2023 0:00	HUN-SOP	MIC
SOP MIC0014	PRELIMINARY FOR THE IDENTIFICATION OF MICROORGANISMS	2	HUN-MIC-Release	10/03/2023 0:00	10/03/2023 0:00	HUN-SOP	MIC
SOP MIC0015	BACTISTAPH LATEX AGGLUTINATION TEST KIT	2	HUN-MIC-Release	10/03/2023 0:00	10/03/2023 0:00	HUN-SOP	MIC
SOP MIC0016	TOTAL VIABLE MESOPHILIC COUNT BACTERIA YEAST AND FUNGI	4	HUN-MIC-Release	7/03/2025 15:51	7/03/2025 15:51	HUN-SOP	MIC
SOP MIC0017	OPERATION OF THE MAS 100NT MICROBIAL AIR SAMPLER	2	HUN-MIC-Release	18/01/2024 0:00	18/01/2024 0:00	HUN-SOP	MIC
SOP MIC0018	ENUMERATION OF STERIKON BIOLOGICAL INDICATOR AMPOULES	2	HUN-MIC-Release	18/03/2023 0:00	18/03/2023 0:00	HUN-SOP	MIC
SOP MIC0019	PREPARATION AND MAINTENANCE OF THE CULTURE COLLECTION	2	HUN-MIC-Release	17/03/2021 0:00	17/03/2021 0:00	HUN-SOP	MIC
SOP MIC0019	PREPARATION AND MAINTENANCE OF THE CULTURE COLLECTION	3	HUN-MIC-Release	16/04/2024 1:00	16/04/2024 1:00	HUN-SOP	MIC
SOP MIC0020	IDENTIFICATION OF SPORES FROM TAPE LIFTS	2	HUN-MIC-Release	18/03/2023 0:00	18/03/2023 0:00	HUN-SOP	MIC
SOP MIC0021	VALIDATION OF PRODUCTS	2	HUN-MIC-Release	5/05/2021 1:00	5/05/2021 1:00	HUN-SOP	MIC
SOP MIC0021	VALIDATION OF PRODUCTS	3	HUN-MIC-Release	15/06/2024 1:00	15/06/2024 1:00	HUN-SOP	MIC
SOP MIC0022	DETERMINATION OF PRESENCE OR ABSENCE OF SALMONELLA SPP.	2	HUN-MIC-Release	18/03/2023 0:00	18/03/2023 0:00	HUN-SOP	MIC
SOP MIC0023	DETERMINATION OF PRESENCE OR ABSENCE OF S. AURES BP	3	HUN-MIC-Release	6/09/2021 1:00	6/09/2021 1:00	HUN-SOP	MIC
SOP MIC0024	WASTE MANAGEMENT PROCEDURE FOR THE MICRO LAB	2	HUN-MIC-Release	2/12/2022 0:00	2/12/2022 0:00	HUN-SOP	MIC
SOP MIC0025	DETERMINATION OF PRESENCE OR ABSENCE OF PS. AERUGINOSA BP	2	HUN-MIC-Release	28/02/2024 0:00	28/02/2024 0:00	HUN-SOP	MIC
SOP MIC0026	OPERATION OF THE PINNACLE LABORATORY FREEZER	2	HUN-MIC-Release	22/02/2024 0:00	22/02/2024 0:00	HUN-SOP	MIC
SOP MIC0027	OPERATION OF THE LUTRON TM 947SD FOUR CHANNEL DATA LOGGER	2	HUN-MIC-Release	16/01/2023 0:00	16/01/2023 0:00	HUN-SOP	MIC
SOP MIC0028	OPERATION OF THE DIGITECH XC0424 DATA LOGGER	2	HUN-MIC-Release	15/01/2023 0:00	15/01/2023 0:00	HUN-SOP	MIC
SOP MIC0029	TEMPERATURE MAPPING OF EQUIPMENT IN THE MICRO LAB	2	HUN-MIC-Release	25/01/2023 0:00	25/01/2023 0:00	HUN-SOP	MIC
SOP MIC0030	MONITORING AND MAINTENANCE OF INCUBATORS AND REFRIGERATORS	2	HUN-MIC-Release	2/12/2022 0:00	2/12/2022 0:00	HUN-SOP	MIC
SOP MIC0031	OPERATION AND CALIBRATION OF LABORATORY TIMERS	3	HUN-MIC-Release	6/02/2024 0:00	6/02/2024 0:00	HUN-SOP	MIC
SOP MIC0032	OPERATION AND VERIFICATION OF MICROPIPETTES	3	HUN-MIC-Release	16/02/2024 0:00	16/02/2024 0:00	HUN-SOP	MIC
SOP MIC0033	CALIBARTAION OF ANALOGUE THERMOMETERS	2	HUN-MIC-Release	8/12/2022 0:00	8/12/2022 0:00	HUN-SOP	MIC
SOP MIC0034	OPERATION OF GILSON MACROMAN	2	HUN-MIC-Release	8/12/2022 0:00	8/12/2022 0:00	HUN-SOP	MIC
SOP MIC0035	OPERATION OF THE ZEISS PRIMOSTAR MICROSCOPE	2	HUN-MIC-Release	8/12/2022 0:00	8/12/2022 0:00	HUN-SOP	MIC
SOP MIC0036	OPERATION AND CALIBRATION OF THE METTLER ML3002T AND ML5002T BALANCES	2	HUN-MIC-Release	15/12/2022 0:00	15/12/2022 0:00	HUN-SOP	MIC
SOP MIC0037	OPERATION OF THE DENSICHECK PLUS NEPHELOMETER	2	HUN-MIC-Release	30/01/2024 0:00	30/01/2024 0:00	HUN-SOP	MIC
SOP MIC0038	OPERATION AND CALIBRATION OF THE METTLER ML204T BALANCE	2	HUN-MIC-Release	15/12/2022 0:00	15/12/2022 0:00	HUN-SOP	MIC
SOP MIC0039	OPERATION OF THE METTLER RS-P25 PRINTER	2	HUN-MIC-Release	15/12/2022 0:00	15/12/2022 0:00	HUN-SOP	MIC
SOP MIC0040	OPERATION OF THE CILMAREC HOTPLATE STIRRER	2	HUN-MIC-Release	15/02/2023 0:00	15/02/2023 0:00	HUN-SOP	MIC
SOP MIC0041	OPERATION OF THE THERMOLINE TWB-24D WATERBATH	1	HUN-MIC-Release	21/02/2020 0:00	21/02/2020 0:00	HUN-SOP	MIC
SOP MIC0042	OPERATION OF THE SEWARD 400 STOMACHER	2	HUN-MIC-Release	15/02/2023 0:00	15/02/2023 0:00	HUN-SOP	MIC
SOP MIC0043	OPERATION OF HERATHERM INCUBATORS AND DRYER	2	HUN-MIC-Release	20/01/2023 0:00	20/01/2023 0:00	HUN-SOP	MIC
SOP MIC0044	OPERATION AND MAINTENANCE OF THE ELIX 3 ADVANTAGE 3 WATER SYSTEM	2	HUN-MIC-Release	15/02/2023 0:00	15/02/2023 0:00	HUN-SOP	MIC
SOP MIC0045	OPERATION AND MAINTENANCE OF THE ULTRASAFE SERIES CLASS II BIOLOGICAL SAFETY CABINET	2	HUN-MIC-Release	25/03/2023 0:00	25/03/2023 0:00	HUN-SOP	MIC
SOP MIC0046	OPERATION OF THE STUART SC6+ COLONY COUNTER	2	HUN-MIC-Release	25/01/2023 0:00	25/01/2023 0:00	HUN-SOP	MIC
SOP MIC0047	OPERATION AND CALIBRATION OF THE CYBER JERBOA CEC5513 ATHERTON AUTOCLAVE	2	HUN-MIC-Release	25/08/2023 1:00	25/08/2023 1:00	HUN-SOP	MIC
SOP MIC0048	CALIBRATION USE AND MAINTENANCE OF THE OAKTON PH 700 METER	2	HUN-MIC-Release	20/02/2023 0:00	20/02/2023 0:00	HUN-SOP	MIC
SOP MIC0049	OPERATION AND MAINTENANCE OF THE HWS 120 LAMINAR FLOW CABINET	2	HUN-MIC-Release	25/01/2023 0:00	25/01/2023 0:00	HUN-SOP	MIC
SOP MIC0050	OPERATION OF THE COLE PARMER VARIABLE SPEED VORTEX MIXER	2	HUN-MIC-Release	25/02/2023 0:00	25/02/2023 0:00	HUN-SOP	MIC
SOP MIC0051	OPERATION OF THE COLE PARMER ULTRASONIC CLEANER	2	HUN-MIC-Release	15/02/2023 0:00	15/02/2023 0:00	HUN-SOP	MIC
SOP MIC0052	OPERATION OF THE AVERY DENNISON MONARCH 1136 LABEL GUN	2	HUN-MIC-Release	20/02/2023 0:00	20/02/2023 0:00	HUN-SOP	MIC
SOP MIC0053	OPERATION OF THE MY TEMP MINI DIGITAL INCUBATOR	2	HUN-MIC-Release	25/08/2023 1:00	25/08/2023 1:00	HUN-SOP	MIC
SOP MIC0054	QUALITY RISK ASSESSMENT IN THE MICROBIOLOGY LABORATORY	2	HUN-MIC-Release	25/01/2023 0:00	25/01/2023 0:00	HUN-SOP	MIC
SOP MIC0055	MICRO LAB INVESTIGATION REPORT VER002	3	HUN-MIC-Release	26/01/2024 0:00	26/01/2024 0:00	HUN-SOP	MIC
SOP MIC0056	INTERNAL AUDIT PROCEDURES FOR THE MICROBIOLOGY LABORATORY	2	HUN-MIC-Release	25/11/2022 0:00	25/11/2022 0:00	HUN-SOP	MIC
SOP MIC0057	GOOD DOCUMENTATION POLICY AND DATA INTEGRITY	2	HUN-MIC-Release	25/01/2023 0:00	25/01/2023 0:00	HUN-SOP	MIC
SOP MIC0058	MANAGEMENT OF THE MICROBIOLOGY CALIBRATION SYSTEM	2	HUN-MIC-Release	15/12/2022 0:00	15/12/2022 0:00	HUN-SOP	MIC
SOP MIC0059	MICROBIOLOGY QUALITY MANUAL	2	HUN-MIC-Release	25/11/2022 0:00	25/11/2022 0:00	HUN-SOP	MIC
SOP MIC0060	BALANCE USE CALIBRATION AND MAINTENANCE	2	HUN-MIC-Release	15/12/2022 0:00	15/12/2022 0:00	HUN-SOP	MIC

SOP MIC0061	GENERATION AND EXECUTION OF INSTALLATION OPERATIONAL AND PERFORMANCE QUALIFICATION PROTOCOLS AND REPORTS	2	HUN-MIC-Release	20/12/2022 0:00	20/12/2022 0:00	HUN-SOP	MIC
SOP MIC0062	QUALIFICATION DEVIATION MANAGEMENT MICRO VALIDATION STUDIES	2	HUN-MIC-Release	25/01/2023 0:00	25/01/2023 0:00	HUN-SOP	MIC
SOP MIC0063	COMPUTER USE POLICY	2	HUN-MIC-Release	25/02/2023 0:00	25/02/2023 0:00	HUN-SOP	MIC
SOP MIC0064	TRAINING STAFF IN THE MICRO LAB	3	HUN-MIC-Release	19/01/2024 0:00	19/01/2024 0:00	HUN-SOP	MIC
SOP MIC0065	RECEIPT AND REGISTRATION OF SAMPLE IN THE MICRO LAB	3	HUN-MIC-Release	8/07/2024 1:00	8/07/2024 1:00	HUN-SOP	MIC
SOP MIC0065	RECEIPT AND REGISTRATION OF SAMPLE IN THE MICRO LAB	2	HUN-MIC-Release	2/07/2021 1:00	2/07/2021 1:00	HUN-SOP	MIC
SOP MIC0066	ISSUING A CERTIFICATE OF ANALYSIS	3	HUN-MIC-Release	21/03/2024 0:00	21/03/2024 0:00	HUN-SOP	MIC
SOP MIC0066	ISSUING A CERTIFICATE OF ANALYSIS	2	HUN-MIC-Release	12/03/2021 0:00	12/03/2021 0:00	HUN-SOP	MIC
SOP MIC0067	LABORATORY NOTEBOOK POLICY	2	HUN-MIC-Release	25/02/2023 0:00	25/02/2023 0:00	HUN-SOP	MIC
SOP MIC0068	ISSUACE USAGE AND CONTROL OF BOUND BOOKS	2	HUN-MIC-Release	25/01/2023 0:00	25/01/2023 0:00	HUN-SOP	MIC
SOP MIC0069	ENVIRONMENTAL MONITORING	2	HUN-MIC-Release	3/11/2021 0:00	3/11/2021 0:00	HUN-SOP	MIC
SOP MIC0070	PREPARATION AND CONTROL OF STANDARD OPERATING PROCEDURE	2	HUN-MIC-Release	26/02/2024 0:00	26/02/2024 0:00	HUN-SOP	MIC
SOP MIC0070	PREPARATION AND CONTROL OF STANDARD OPERATING PROCEDURE	1	HUN-MIC-Release	30/09/2020 1:00	30/09/2020 1:00	HUN-SOP	MIC
SOP MIC0071	ENUMERATION PF COLIFORM GB	2	HUN-MIC-Release	6/09/2021 1:00	6/09/2021 1:00	HUN-SOP	MIC
SOP MIC0072	OPERSTION OF THE SENTINO FILTER DISPENSER	2	HUN-MIC-Release	26/02/2024 0:00	26/02/2024 0:00	HUN-SOP	MIC
SOP MIC0073	OPERATION OF THE PALL LABORATORY MANIFOLD	2	HUN-MIC-Release	14/02/2024 0:00	14/02/2024 0:00	HUN-SOP	MIC
SOP MIC0074	EXAMINATION OF PROCESS WATER BY MEMBRANE FILTRATION	3	HUN-MIC-Release	15/09/2021 1:00	15/09/2021 1:00	HUN-SOP	MIC
SOP PRD0001	Freezer and freeze dryer SOP	4	HUN-PRD-Release	8/12/2023 0:00	8/12/2023 0:00	HUN-SOP	PRD
SOP PRD0002	Material Dispensary	4	HUN-PRD-Release	18/07/2023 1:00	18/07/2023 1:00	HUN-SOP	PRD
SOP PRD0003	Cooking Machine SOP	3	HUN-PRD-Release	9/01/2024 0:00	9/01/2024 0:00	HUN-SOP	PRD
SOP PRD0004	Heat Exchanger	2	HUN-PRD-Release	9/01/2024 0:00	9/01/2024 0:00	HUN-SOP	PRD
SOP PRD0005	Aeration Machine Operation	1	HUN-PRD-Release	18/07/2019 1:00	18/07/2019 1:00	HUN-SOP	PRD
SOP PRD0006	Depositor Machine Opearation	1	HUN-PRD-Release	18/07/2019 1:00	18/07/2019 1:00	HUN-SOP	PRD
SOP PRD0007	De-molding, Sorting and Bulk Packing	2	HUN-PRD-Release	24/08/2023 1:00	24/08/2023 1:00	HUN-SOP	PRD
SOP PRD0008	Heat Sealer Operation	2	HUN-PRD-Release	24/11/2023 0:00	24/11/2023 0:00	HUN-SOP	PRD
SOP PRD0009	Start up and operation of x-ray inspection machine	3	HUN-PRD-Release	19/01/2024 0:00	19/01/2024 0:00	HUN-SOP	PRD
SOP PRD0010	Mold and tray wash using ultra sonic machine	1	HUN-PRD-Release	18/07/2019 1:00	18/07/2019 1:00	HUN-SOP	PRD
SOP PRD0011	Leak-Test Machine	3	HUN-PRD-Release	19/09/2023 1:00	19/09/2023 1:00	HUN-SOP	PRD
SOP PRD0013	General Cleaning	4	HUN-PRD-Release	23/06/2022 1:00	23/06/2022 1:00	HUN-SOP	PRD
SOP PRD0014	Freezer and freeze dryer Cleaning	1	HUN-PRD-Release	24/08/2023 1:00	24/08/2023 1:00	HUN-SOP	PRD
SOP PRD0015	SOP for A&D Checkweigher	2	HUN-PRD-Release	31/08/2023 1:00	31/08/2023 1:00	HUN-SOP	PRD
SOP PRD0017	SOP For SLE-64040 RO Water System Sanitisation	2	HUN-PRD-Release	21/04/2021 1:00	21/04/2021 1:00	HUN-SOP	PRD
SOP PRD0018	Bulk and Packed Product Storage	1	HUN-PRD-Release	24/08/2023 1:00	24/08/2023 1:00	HUN-SOP	PRD
SOP PRD0019	Portable CIP Machine Procedure	1	HUN-PRD-Release	25/02/2020 0:00	25/02/2020 0:00	HUN-SOP	PRD
SOP PRD0020	SLE-64040 RO Water System Operation	3	HUN-PRD-Release	31/08/2023 1:00	31/08/2023 1:00	HUN-SOP	PRD
SOP PRD0021	Shield Allegro Xray Machine	2	HUN-PRD-Release	5/08/2020 1:00	5/08/2020 1:00	HUN-SOP	PRD
SOP PRD0022	800 L Stirrer operation	2	HUN-PRD-Release	18/09/2023 1:00	18/09/2023 1:00	HUN-SOP	PRD
SOP PRD0023	Labelling Machine Operation	1	HUN-PRD-Release	24/08/2023 1:00	24/08/2023 1:00	HUN-SOP	PRD
SOP PRD0024	Sifter Machine	1	HUN-PRD-Release	30/06/2020 1:00	30/06/2020 1:00	HUN-SOP	PRD
SOP PRD0025	Powder Liquid Mixer	1	HUN-PRD-Release	17/07/2020 1:00	17/07/2020 1:00	HUN-SOP	PRD
SOP PRD0026	Dry Powder Blender	1	HUN-PRD-Release	17/08/2020 1:00	17/08/2020 1:00	HUN-SOP	PRD
SOP PRD0027	Washing Machine SOP	2	HUN-PRD-Release	12/09/2024 14:26	12/09/2024 14:26	HUN-SOP	PRD
SOP PRD0028	IRE Mixer SOP	1	HUN-PRD-Release	24/09/2020 1:00	24/09/2020 1:00	HUN-SOP	PRD
SOP PRD0029	Freeze Dryer 2 SOP	1	HUN-PRD-Release	13/11/2020 0:00	13/11/2020 0:00	HUN-SOP	PRD
SOP PRD0030	Production Line Start-up and Clearance	1	HUN-PRD-Release	30/12/2020 0:00	30/12/2020 0:00	HUN-SOP	PRD
SOP PRD0031	SOP for OMORI S-5010EU-BX Flow Wrapper	1	HUN-PRD-Release	17/07/2020 1:00	17/07/2020 1:00	HUN-SOP	PRD
SOP PRD0032	FD Checkweigher 2 SOP	2	HUN-PRD-Release	11/01/2021 0:00	11/01/2021 0:00	HUN-SOP	PRD
SOP CL0001	Cleaning of Offices/Lunch Room/Windows/Doors and Floors	2	HUN-PRD-Release	19/01/2024 0:00	19/01/2024 0:00	HUN-SOP	CL
SOP PRD0033	Flowrapper 3	1	HUN-PRD-Release	20/06/2022 1:00	20/06/2022 1:00	HUN-SOP	PRD
SOP PRD0035	Tablet Press Sejong MRC-30N	2	HUN-PRD-Release	20/02/2025 17:01	20/02/2025 17:01	HUN-SOP	PRD
SOP PRD0036	Operation and Cleaning of Metal Detector	3	HUN-PRD-Release	10/03/2025 16:33	10/03/2025 16:33	HUN-SOP	PRD
SOP CL0002	Cleaning Requirements for the Male & Female Amenities	2	HUN-PRD-Release	19/01/2024 0:00	19/01/2024 0:00	HUN-SOP	CL
SOP CL0003	Cleaning of washbay and dry storage room	3	HUN-PRD-Release	17/02/2023 0:00	17/02/2023 0:00	HUN-SOP	CL
SOP PRD0037	Operation and Cleaning Procedure for Tablet Deduster	2	HUN-PRD-Release	10/03/2025 15:47	10/03/2025 15:47	HUN-SOP	PRD
SOP PRD0038	Electro Lab Hardness Tester EHT-5PR	2	HUN-PRD-Release	10/03/2025 14:48	10/03/2025 14:48	HUN-SOP	PRD
SOP CL0004	Approved Cleaning Chemicals Agents	4	HUN-PRD-Release	25/03/2022 0:00	25/03/2022 0:00	HUN-SOP	CL
SOP PRD0039	Operation and Cleaning procedure of Friability Test Machine	2	HUN-PRD-Release	10/03/2025 16:07	10/03/2025 16:07	HUN-SOP	PRD
SOP PRD0040	Operation and Cleaning Procedure of Disintegration Machine	2	HUN-PRD-Release	10/03/2025 16:20	10/03/2025 16:20	HUN-SOP	PRD
SOP PRD0041	Operation and Cleaning Procedure of Weighing Balance	2	HUN-PRD-Release	10/03/2025 16:27	10/03/2025 16:27	HUN-SOP	PRD
SOP PRD0042	The Operating and Cleaning Procedre of Russell Sieving Machine	2	HUN-PRD-Release	13/05/2022 1:00	13/05/2022 1:00	HUN-SOP	PRD
SOP PRD0043	The Operating and Cleaning Procedre of Sejong Coating Machine	2	HUN-PRD-Release	27/05/2022 1:00	27/05/2022 1:00	HUN-SOP	PRD
SOP PRD0044	Operation and Cleaning of Anish Fluid Bed (AFB) Dryer	2	HUN-PRD-Release	5/07/2023 1:00	5/07/2023 1:00	HUN-SOP	PRD
SOP PRD0045	Operation and Cleaning of Rapid Mixture Granulator (RMG) Machine	2	HUN-PRD-Release	13/05/2022 1:00	13/05/2022 1:00	HUN-SOP	PRD
SOP PRD0046	The Cleaning and Opration Procedure of Automatic Encapsulation (NJP series)	1	HUN-PRD-Release	24/04/2022 1:00	24/04/2022 1:00	HUN-SOP	PRD
SOP PRD0047	General Cleaning - Tablet Line	2	HUN-PRD-Release	22/08/2022 1:00	22/08/2022 1:00	HUN-SOP	PRD

SOP PRD0048	Operation of YHA-2A Blender	1	HUN-PRD-Release	27/04/2022 1:00	27/04/2022 1:00	HUN-SOP	PRD
SOP PRD0049	Operation and cleaning Procedure Of YHA Portable Dry Powder Blender (Model: WHJ-100)	1	HUN-PRD-Release	19/07/2023 1:00	19/07/2023 1:00	HUN-SOP	PRD
SOP PRD0053	Operation and cleaning of Tablet counting machine	1	HUN-PRD-Release	20/06/2023 1:00	20/06/2023 1:00	HUN-SOP	PRD
SOP PRD0054	Operation and cleaning of Semi-auto capping machine	1	HUN-PRD-Release	20/06/2023 1:00	20/06/2023 1:00	HUN-SOP	PRD
SOP PRD0055	Operation and Cleaning Procedure for Tablet Counting and Filling Machine	1	HUN-PRD-Release	21/08/2023 1:00	21/08/2023 1:00	HUN-SOP	PRD
SOP PRD0056	Operation and Cleaning of Labelling Machine (Square Bottle) (CAL830,831,832)	1	HUN-PRD-Release	21/08/2023 1:00	21/08/2023 1:00	HUN-SOP	PRD
SOP PRD0057	Operation and Cleaning of Shark Capping machine	1	HUN-PRD-Release	22/03/2024 0:00	22/03/2024 0:00	HUN-SOP	PRD
SOP PRD0058	Operation and Cleaning of BP600AR Shrink Wrapper	1	HUN-PRD-Release	22/03/2024 0:00	22/03/2024 0:00	HUN-SOP	PRD
SOP PRD0060	Handling of Ethanol in Production Area	1	HUN-PRD-Release	21/02/2024 0:00	21/02/2024 0:00	HUN-SOP	PRD
SOP PRD0062	Packing Line Start-up and Clearance	2	HUN-PRD-Release	26/06/2023 1:00	26/06/2023 1:00	HUN-SOP	PRD
SOP PRD0063	Milk Powder Filling Machine	1	HUN-PRD-Release	28/05/2020 1:00	28/05/2020 1:00	HUN-SOP	PRD
SOP PRD0064	Induction sealer Operation	2	HUN-PRD-Release	24/11/2023 0:00	24/11/2023 0:00	HUN-SOP	PRD
SOP PRD0065	Videojet 1620 coder	1	HUN-PRD-Release	4/06/2020 1:00	4/06/2020 1:00	HUN-SOP	PRD
SOP PRD0066	SMART Sealing Machine Operation	1	HUN-PRD-Release	22/06/2020 1:00	22/06/2020 1:00	HUN-SOP	PRD
SOP PRD0068	3M Case Sealer	1	HUN-PRD-Release	30/06/2020 1:00	30/06/2020 1:00	HUN-SOP	PRD
SOP PRD0069	Joyo Can Seamer Operation	1	HUN-PRD-Release	12/08/2020 1:00	12/08/2020 1:00	HUN-SOP	PRD
SOP PRD0070	Vacuum System For Milk Powder Line	1	HUN-PRD-Release	14/08/2020 1:00	14/08/2020 1:00	HUN-SOP	PRD
SOP PRD0071	Joyo Can Seamer 2	1	HUN-PRD-Release	17/02/2021 0:00	17/02/2021 0:00	HUN-SOP	PRD
SOP PRD0072	SOP For YHA Blender	1	HUN-PRD-Release	1/02/2021 0:00	1/02/2021 0:00	HUN-SOP	PRD
SOP PRD0073	Operation and Cleaning of FVC-1 Vacuum Conveyor	1	HUN-PRD-Release	17/06/2021 1:00	17/06/2021 1:00	HUN-SOP	PRD
SOP PRD0074	Operation and Cleaning of Automatic L-sealer Wrapping Machine	1	HUN-PRD-Release	1/12/2023 0:00	1/12/2023 0:00	HUN-SOP	PRD
SOP PRD0075	SOP for Single Stick Machine	1	HUN-PRD-Release	3/05/2021 1:00	3/05/2021 1:00	HUN-SOP	PRD
SOP PRD0076	General Cleaning - Sachet Line	1	HUN-PRD-Release	13/07/2021 1:00	13/07/2021 1:00	HUN-SOP	PRD
SOP PRD0077	Operation of Yihua YHA-2A Blender	1	HUN-PRD-Release	13/07/2021 1:00	13/07/2021 1:00	HUN-SOP	PRD
SOP PRD0078	Inspection and operation of sieve and mesh	2	HUN-PRD-Release	13/05/2022 1:00	13/05/2022 1:00	HUN-SOP	PRD
SOP PRD0079	Operation and Cleaning of Grinding Machine	2	HUN-PRD-Release	19/06/2023 1:00	19/06/2023 1:00	HUN-SOP	PRD
SOP PRD0080	Operation and Cleaning of Milling Machine	1	HUN-PRD-Release	10/08/2021 1:00	10/08/2021 1:00	HUN-SOP	PRD
SOP PRD0081	Operation and Cleaning of 12-Lane Machine	2	HUN-PRD-Release	28/02/2022 0:00	28/02/2022 0:00	HUN-SOP	PRD
SOP PRD0082	Operation and Checking of X-Ray Machine	1	HUN-PRD-Release	16/08/2021 1:00	16/08/2021 1:00	HUN-SOP	PRD
SOP PRD0084	Operation and Cleaning of KNS-500/5 8-Lane Machine	1	HUN-PRD-Release	14/03/2022 0:00	14/03/2022 0:00	HUN-SOP	PRD
SOP CL0005	Cleaning of mops, buckets, brooms, brushes & related cleaning equipment	1	HUN-PRD-Release	14/03/2024 0:00	14/03/2024 0:00	HUN-SOP	CL
SOP CL0006	Use of cleaning status tags and room logs	3	HUN-PRD-Release	24/05/2024 1:00	24/05/2024 1:00	HUN-SOP	CL
SOP PRD0086	Operation of Leak Test Machine	2	HUN-PRD-Release	10/08/2023 1:00	10/08/2023 1:00	HUN-SOP	PRD
SOP PRD0089	Handling Probiotics	1	HUN-PRD-Release	14/09/2022 1:00	14/09/2022 1:00	HUN-SOP	PRD
SOP PRD0094	Operation and Cleaning Procedure for Shark Line Capping Machine	1	HUN-PRD-Release	22/03/2024 0:00	22/03/2024 0:00	HUN-SOP	PRD
SOP PRD0095	OPERATION AND CLEANING PROCEDURE OF SHARK SHRINK MACHINE (CAL593)	1	HUN-PRD-Release	22/04/2024 1:00	22/04/2024 1:00	HUN-SOP	PRD
SOP QA0001	Document Control	8	HUN-QA-Release	14/10/2024 15:57	14/10/2024 15:57	HUN-SOP	QA
SOP QA0002	Good Manufacturing Practice	3	HUN-QA-Release	9/03/2023 0:00	9/03/2023 0:00	HUN-SOP	QA
SOP QA0003	Guidelines for Preparing GMP Agreement	2	HUN-QA-Release	24/10/2022 0:00	24/10/2022 0:00	HUN-SOP	QA
SOP QA0004	Training Program	5	HUN-QA-Release	14/10/2024 16:50	14/10/2024 16:50	HUN-SOP	QA
SOP QA0005	Change Control Procedure	5	HUN-QA-Release	17/02/2023 0:00	17/02/2023 0:00	HUN-SOP	QA
SOP QA0006	Quality Incident/ Deviation Procedure	3	HUN-QA-Release	26/07/2024 1:00	26/07/2024 1:00	HUN-SOP	QA
SOP QA0007	Quality Risk Management	3	HUN-QA-Release	30/06/2022 1:00	30/06/2022 1:00	HUN-SOP	QA
SOP QA0008	Internal Audit	6	HUN-QA-Release	1/11/2024 10:24	1/11/2024 10:24	HUN-SOP	QA
SOP QA0009	Calibration Procedure	3	HUN-QA-Release	27/05/2022 1:00	27/05/2022 1:00	HUN-SOP	QA
SOP QA0010	Recall Procedure	7	HUN-QA-Release	9/12/2024 15:09	9/12/2024 15:09	HUN-SOP	QA
SOP QA0011	Pest Control	3	HUN-QA-Release	27/09/2022 1:00	27/09/2022 1:00	HUN-SOP	QA
SOP QA0012	Reject Items Procedure	3	HUN-QA-Release	22/04/2024 1:00	22/04/2024 1:00	HUN-SOP	QA
SOP QA0013	Customer Complaints Management	4	HUN-QA-Release	12/12/2024 15:17	12/12/2024 15:17	HUN-SOP	QA
SOP QA0014	Water Quality Monitoring	6	HUN-QA-Release	6/07/2023 1:00	6/07/2023 1:00	HUN-SOP	QA
SOP QA0015	Management Meetings	3	HUN-QA-Release	23/04/2024 1:00	23/04/2024 1:00	HUN-SOP	QA
SOP QA0016	Registers	3	HUN-QA-Release	24/06/2022 1:00	24/06/2022 1:00	HUN-SOP	QA
SOP QA0017	New Product Introduction	3	HUN-QA-Release	11/12/2024 9:20	11/12/2024 9:20	HUN-SOP	QA
SOP QA0018	Environmental Monitoring Procedure	8	HUN-QA-Release	8/08/2022 1:00	8/08/2022 1:00	HUN-SOP	QA
SOP QA0019	Receiving and Dispatching Export Dairy Goods	5	HUN-QA-Release	23/04/2024 1:00	23/04/2024 1:00	HUN-SOP	QA
SOP QA0020	Label Requirements for Export Dairy Goods	3	HUN-QA-Release	18/07/2023 1:00	18/07/2023 1:00	HUN-SOP	QA
SOP QA0021	Sampling and Testing of Export Dairy Goods	3	HUN-QA-Release	22/04/2024 1:00	22/04/2024 1:00	HUN-SOP	QA
SOP QA0022	GMP Control of Pre-Printed Labels & Pre-Printed Packaging Components	4	HUN-QA-Release	5/12/2023 0:00	5/12/2023 0:00	HUN-SOP	QA
SOP QA0023	Out Of Specification Procedure (OOS)	2	HUN-QA-Release	23/11/2022 0:00	23/11/2022 0:00	HUN-SOP	QA
SOP QA0024	Rework Procedure	4	HUN-QA-Release	9/12/2024 15:05	9/12/2024 15:05	HUN-SOP	QA
SOP QA0025	Returned Goods Procedure	3	HUN-QA-Release	18/01/2024 0:00	18/01/2024 0:00	HUN-SOP	QA
SOP QA0026	Supplier/ Manufacturer QualificationApproval Procedure	5	HUN-QA-Release	25/07/2023 1:00	25/07/2023 1:00	HUN-SOP	QA
SOP QA0028	Product Quality Review	4	HUN-QA-Release	4/12/2024 14:46	4/12/2024 14:46	HUN-SOP	QA
SOP QA0029	Release For Finish Product	3	HUN-QA-Release	23/04/2024 1:00	23/04/2024 1:00	HUN-SOP	QA
SOP QA0030	Operation and Calibration of Water Activity Meter	2	HUN-QA-Release	21/10/2022 0:00	21/10/2022 0:00	HUN-SOP	QA

SOP QA0031	Operation of Hygiena Ensure Touch	3	HUN-QA-Release	22/04/2024 1:00	22/04/2024 1:00	HUN-SOP	QA
SOP QA0032	Calibration/ Performance Check of Scales	2	HUN-QA-Release	27/05/2022 1:00	27/05/2022 1:00	HUN-SOP	QA
SOP QA0033	Operation and Calibration of Moisture Balance	3	HUN-QA-Release	22/04/2024 1:00	22/04/2024 1:00	HUN-SOP	QA
SOP QA0034	Label Requirements for Use	6	HUN-QA-Release	7/12/2021 0:00	16/01/2023 0:00	HUN-SOP	QA
SOP QA0035	Data Integrity and Security	1	HUN-QA-Release	26/10/2022 0:00	26/10/2023 0:00	HUN-SOP	QA
SOP QA0036	Batch Register	1	HUN-QA-Release	31/10/2022 0:00	31/10/2022 0:00	HUN-SOP	QA
SOP QA0037	In-process Checks	2	HUN-QA-Release	29/08/2022 1:00	29/08/2022 1:00	HUN-SOP	QA
SOP QA0038	Sampling, Testing, Releasing and Retention of Raw Material	4	HUN-QA-Release	4/12/2024 12:54	4/12/2024 12:54	HUN-SOP	QA
SOP QA0039	Corrective and Preventive Action (CAPA)	3	HUN-QA-Release	20/01/2023 0:00	20/01/2023 0:00	HUN-SOP	QA
SOP QA0040	Use and handling of MWO & PWO	2	HUN-QA-Release	21/04/2022 1:00	21/04/2022 1:00	HUN-SOP	QA
SOP QA0041	Reconciliation	3	HUN-QA-Release	26/07/2024 1:00	26/07/2024 1:00	HUN-SOP	QA
SOP QA0042	Stability Studies Procedure	3	HUN-QA-Release	12/12/2024 15:20	12/12/2024 15:20	HUN-SOP	QA
SOP QA0043	Handling of Retest/Expired Extension of Raw Material	2	HUN-QA-Release	17/01/2023 0:00	17/01/2023 0:00	HUN-SOP	QA
SOP QA0044	Monitoring of Purified Water	4	HUN-QA-Release	17/05/2022 1:00	17/05/2022 1:00	HUN-SOP	QA
SOP QA0045	Vistor Management	2	HUN-QA-Release	23/04/2024 1:00	23/04/2024 1:00	HUN-SOP	QA
SOP QA0046	Code Creation Procedure	2	HUN-QA-Release	12/12/2024 15:23	12/12/2024 15:23	HUN-SOP	QA
SOP QA0047	Operation and Calibration of Label Counter	2	HUN-QA-Release	5/12/2024 17:07	5/12/2024 17:07	HUN-SOP	QA
SOP QA0048	Taste and Colour Testing Procedure	2	HUN-QA-Release	2/08/2024 1:00	2/08/2024 1:00	HUN-SOP	QA
SOP QA0049	Control of Tablet Machine Tooling	1	HUN-QA-Release	7/12/2022 0:00	7/12/2022 0:00	HUN-SOP	QA
SOP QA0051	Halal Manual	3	HUN-QA-Release	17/10/2024 9:03	17/10/2024 9:03	HUN-SOP	QA
SOP QA0052	Rotational Testing of Bulk Products and Finished Products	1	HUN-QA-Release	16/08/2023 1:00	16/08/2023 1:00	HUN-SOP	QA
SOP QC0001	Preparation and Control of Standard Operating Procedures	2	HUN-QC-Release	6/02/2023 0:00	6/02/2023 0:00	HUN-SOP	QC
SOP QC0002	Laboratory Good Documentation Practices and Data integrity	2	HUN-QC-Release	7/02/2023 0:00	7/02/2023 0:00	HUN-SOP	QC
SOP QC0003	Good Laboratory Practices	2	HUN-QC-Release	7/02/2023 0:00	7/02/2023 0:00	HUN-SOP	QC
SOP QC0004	Issuance usage and control of bound books	2	HUN-QC-Release	7/02/2023 0:00	7/02/2023 0:00	HUN-SOP	QC
SOP QC0005	Document Issue and Results Reporting	4	HUN-QC-Release	6/02/2023 0:00	6/02/2023 0:00	HUN-SOP	QC
SOP QC0006	Employee induction and training Record Procedure	2	HUN-QC-Release	19/06/2023 1:00	19/06/2023 1:00	HUN-SOP	QC
SOP QC0007	Preparation and Control of Analytical Test Procedure and Analytical Test worksheet	3	HUN-QC-Release	8/02/2023 0:00	8/02/2023 0:00	HUN-SOP	QC
SOP QC0008	Review of Pharmacopeia Update	2	HUN-QC-Release	8/02/2023 0:00	8/02/2023 0:00	HUN-SOP	QC
SOP QC0009	Equipments usage and Calibration Requirements	2	HUN-QC-Release	8/02/2023 0:00	8/02/2023 0:00	HUN-SOP	QC
SOP QC0010	Instrument Repair and Maintenance	3	HUN-QC-Release	28/08/2023 1:00	28/08/2023 1:00	HUN-SOP	QC
SOP QC0011	Laboraoty computer systems and software management	2	HUN-QC-Release	19/06/2023 1:00	19/06/2023 1:00	HUN-SOP	QC
SOP QC0012	Validation and usage of Excel calculation Worksheet	2	HUN-QC-Release	9/02/2023 0:00	9/02/2023 0:00	HUN-SOP	QC
SOP QC0013	Handling of Laboratory Standards	2	HUN-QC-Release	28/04/2022 1:00	28/04/2022 1:00	HUN-SOP	QC
SOP QC0014	Review of Analytical Document	2	HUN-QC-Release	9/02/2023 0:00	9/02/2023 0:00	HUN-SOP	QC
SOP QC0015	Receipt and Handling of QC Samples (Raw Material, Finished Products, Analytical Request)	2	HUN-QC-Release	9/02/2023 0:00	9/02/2023 0:00	HUN-SOP	QC
SOP QC0016	Responsibilities of Quality Control Department	2	HUN-QC-Release	9/02/2023 0:00	9/02/2023 0:00	HUN-SOP	QC
SOP QC0017	Good Chromatography Practices	3	HUN-QC-Release	28/08/2023 1:00	28/08/2023 1:00	HUN-SOP	QC
SOP QC0018	Handing of Out of Specification (OOS) Laboratory Result	3	HUN-QC-Release	7/09/2022 1:00	7/09/2022 1:00	HUN-SOP	QC
SOP QC0019	Laboratory Incidents	2	HUN-QC-Release	10/02/2023 0:00	10/02/2023 0:00	HUN-SOP	QC
SOP QC0020	Validation Master Plan-Quality Control Department	2	HUN-QC-Release	10/02/2023 0:00	10/02/2023 0:00	HUN-SOP	QC
SOP QC0021	Validation of Analytical Methods	2	HUN-QC-Release	28/04/2022 1:00	28/04/2022 1:00	HUN-SOP	QC
SOP QC0022	Analytical Method Transfer	2	HUN-QC-Release	10/02/2023 0:00	10/02/2023 0:00	HUN-SOP	QC
SOP QC0024	Laboratory Safety	2	HUN-QC-Release	10/02/2023 0:00	10/02/2023 0:00	HUN-SOP	QC
SOP QC0025	Dangerous Goods Handing and Storage	2	HUN-QC-Release	13/02/2023 0:00	13/02/2023 0:00	HUN-SOP	QC
SOP QC0026	Handling of Laboratory Chemicals	3	HUN-QC-Release	28/08/2023 1:00	28/08/2023 1:00	HUN-SOP	QC
SOP QC0027	Handling Laboratory Glassware	2	HUN-QC-Release	13/02/2023 0:00	13/02/2023 0:00	HUN-SOP	QC
SOP QC0028	Glassware Washup	2	HUN-QC-Release	13/02/2023 0:00	13/02/2023 0:00	HUN-SOP	QC
SOP QC0029	Timer Calibration	2	HUN-QC-Release	14/02/2023 0:00	14/02/2023 0:00	HUN-SOP	QC
SOP QC0030	Handling of Third party and Special request analysis	2	HUN-QC-Release	14/02/2023 0:00	14/02/2023 0:00	HUN-SOP	QC
SOP QC0031	Analyst Qualification	2	HUN-QC-Release	14/02/2023 0:00	14/02/2023 0:00	HUN-SOP	QC
SOP QC0032	Operation and calibration of Balance	2	HUN-QC-Release	14/02/2023 0:00	14/02/2023 0:00	HUN-SOP	QC
SOP QC0033	Operation, Maintenance and Calibration of Ultrasonic Bath	2	HUN-QC-Release	19/06/2023 1:00	19/06/2023 1:00	HUN-SOP	QC
SOP QC0034	Operation, Maintenance and Calibration of Dry Bath	2	HUN-QC-Release	14/02/2023 0:00	14/02/2023 0:00	HUN-SOP	QC
SOP QC0035	Operation, Maintenance and Calibration of Micropipettes	2	HUN-QC-Release	14/02/2023 0:00	14/02/2023 0:00	HUN-SOP	QC
SOP QC0036	Operation and Calibration of Drying oven -Heratherm OMS 180	2	HUN-QC-Release	15/02/2023 0:00	15/02/2023 0:00	HUN-SOP	QC
SOP QC0037	Operation and Maintenance of UHPLC	3	HUN-QC-Release	6/03/2024 0:00	6/03/2024 0:00	HUN-SOP	QC
SOP QC0038	Operation and Maintenance of Gas Chromatography	2	HUN-QC-Release	6/03/2024 0:00	6/03/2024 0:00	HUN-SOP	QC
SOP QC0039	Basic Operation and Maintenance of Inductively Coupled Plasma Optical Emission Spectrometer	3	HUN-QC-Release	6/03/2024 0:00	6/03/2024 0:00	HUN-SOP	QC
SOP QC0040	Installation and Maintenance of Gas Cylinder	2	HUN-QC-Release	19/06/2023 1:00	19/06/2023 1:00	HUN-SOP	QC
SOP QC0041	Operation and Maintenance of Dynaflow Fume Cupboard	2	HUN-QC-Release	20/06/2023 1:00	20/06/2023 1:00	HUN-SOP	QC
SOP QC0042	Laboratory Notebook	2	HUN-QC-Release	15/02/2023 0:00	15/02/2023 0:00	HUN-SOP	QC
SOP QC0043	Audit of Contract Laboratory	2	HUN-QC-Release	15/02/2023 0:00	15/02/2023 0:00	HUN-SOP	QC
SOP QC0044	Contract Testing	2	HUN-QC-Release	15/02/2023 0:00	15/02/2023 0:00	HUN-SOP	QC
SOP QC0045	Validation Life cycle management of Laboratory Equipments	2	HUN-QC-Release	28/04/2022 1:00	28/04/2022 1:00	HUN-SOP	QC

SOP QC0046	Operation of the Eppendorf Centrifuge	2	HUN-QC-Release	20/06/2023 1:00	20/06/2023 1:00	HUN-SOP	QC
SOP QC0047	Operation and Calibration of the Polarimeter	2	HUN-QC-Release	20/06/2023 1:00	20/06/2023 1:00	HUN-SOP	QC
SOP QC0048	Operation and Calibration of Disintegration test apparatus	1	HUN-QC-Release	18/05/2020 1:00	18/05/2020 1:00	HUN-SOP	QC
SOP QC0049	Operation and Calibration of Sieve Shaker	2	HUN-QC-Release	20/06/2023 1:00	20/06/2023 1:00	HUN-SOP	QC
SOP QC0050	Operation and Calibration of Brookfield Viscometer	2	HUN-QC-Release	22/06/2023 1:00	22/06/2023 1:00	HUN-SOP	QC
SOP QC0051	Operation and Calibration of Refractive Index apparatus	2	HUN-QC-Release	22/06/2023 1:00	22/06/2023 1:00	HUN-SOP	QC
SOP QC0052	Operation and Calibration of Melting Point apparatus	2	HUN-QC-Release	22/06/2023 1:00	22/06/2023 1:00	HUN-SOP	QC
SOP QC0053	Operation and Maintenance of Laboratory Water Purification System	2	HUN-QC-Release	22/06/2023 1:00	22/06/2023 1:00	HUN-SOP	QC
SOP QC0054	Operation of EC 2000 Gardner Kit	2	HUN-QC-Release	22/06/2023 1:00	22/06/2023 1:00	HUN-SOP	QC
SOP QC0055	Operation and Calibration of Mettler Toledo V10S KF Titrator	2	HUN-QC-Release	22/06/2023 1:00	22/06/2023 1:00	HUN-SOP	QC
SOP QC0056	Operation and Calibration of Mettler Toledo G20S Compact Titrator	2	HUN-QC-Release	26/06/2023 1:00	26/06/2023 1:00	HUN-SOP	QC
SOP QC0057	Operation and Maintenance of Scorched Particles Apparatus (ADPI)	2	HUN-QC-Release	26/06/2023 1:00	26/06/2023 1:00	HUN-SOP	QC
SOP QC0058	Operation and Calibration of Vacuum oven-Labec VO3	1	HUN-QC-Release	18/05/2020 1:00	18/05/2020 1:00	HUN-SOP	QC
SOP QC0059	Operation and Calibration of Muffle furnace	2	HUN-QC-Release	26/06/2023 1:00	26/06/2023 1:00	HUN-SOP	QC
SOP QC0060	Operation and Calibration of Agilent Cary 60 UV-Visible spectrophotometer	2	HUN-QC-Release	26/06/2023 1:00	26/06/2023 1:00	HUN-SOP	QC
SOP QC0061	Operation and Calibration of Agilent Cary 630 FTIR	2	HUN-QC-Release	26/06/2023 1:00	26/06/2023 1:00	HUN-SOP	QC
SOP QC0062	Operation and Calibration of Orion Star A211 pH meter	2	HUN-QC-Release	26/06/2023 1:00	26/06/2023 1:00	HUN-SOP	QC
SOP QC0063	Operation and Calibration of Orion Star A112 Conductivity Meter	2	HUN-QC-Release	26/06/2023 1:00	26/06/2023 1:00	HUN-SOP	QC
SOP QC0064	Operation, Maintenance and Calibration of Water Bath	2	HUN-QC-Release	26/06/2023 1:00	26/06/2023 1:00	HUN-SOP	QC
SOP QC0065	Operation of AMP Gas Detector	2	HUN-QC-Release	26/06/2023 1:00	26/06/2023 1:00	HUN-SOP	QC
SOP QC0066	HW-SOP-QC-0066-V001-Operation and Calibration of Water Activity meter	1	HUN-QC-Release	3/05/2022 1:00	3/05/2022 1:00	HUN-SOP	QC
SOP QC0067	HW-SOP-QC-0067-V001-Operation and Calibration of High-Performance Thin Layer Chromatography Systems	1	HUN-QC-Release	19/05/2022 1:00	19/05/2022 1:00	HUN-SOP	QC
SOP QC0068	HW-SOP-QC-0068-V001-Operation and User Management of Agilent Open Lab Software	1	HUN-QC-Release	16/05/2023 1:00	16/05/2023 1:00	HUN-SOP	QC
SOP QC0073	Operation and Maintenance of Laboratory Fridge & Freezer	1	HUN-QC-Release	28/01/2025 15:31	28/01/2025 15:31	HUN-SOP	QC
SOP VAL0001	Validation Master Plan	5	HUN-VAL-Release	16/05/2022 1:00	16/05/2022 1:00	HUN-SOP	VAL
SOP VAL0002	Installation and Operational Qualification Protocol	2	HUN-VAL-Release	2/03/2023 0:00	2/03/2023 0:00	HUN-SOP	VAL
SOP VAL0003	Validation Process	2	HUN-VAL-Release	2/03/2023 0:00	2/03/2023 0:00	HUN-SOP	VAL
SOP VAL0004	Computerised System Validation Master Plan	2	HUN-VAL-Release	24/06/2022 1:00	24/06/2022 1:00	HUN-SOP	VAL
SOP WHS0001	WAREHOUSE STAFF ORIENTATION	2	HUN-WHS-Release	16/10/2024 11:10	16/10/2024 11:10	HUN-SOP	WHS
SOP WHS0002	RECEIVING ITEMS	4	HUN-WHS-Release	16/10/2024 11:18	16/10/2024 11:18	HUN-SOP	WHS
SOP WHS0003	Sampling Result Sheet	3	HUN-WHS-Release	16/10/2024 11:25	16/10/2024 11:25	HUN-SOP	WHS
SOP WHS0004	Goods Receivable Register	2	HUN-WHS-Release	16/10/2024 11:28	16/10/2024 11:28	HUN-SOP	WHS
SOP WHS0005	Warehouse Designated Areas	3	HUN-WHS-Release	16/10/2024 11:32	16/10/2024 11:32	HUN-SOP	WHS
SOP WHS0006	Stock Movements In Warehouse	4	HUN-WHS-Release	16/10/2024 11:41	16/10/2024 11:41	HUN-SOP	WHS
SOP WHS0007	Material Requisition and Picking	4	HUN-WHS-Release	16/10/2024 11:45	16/10/2024 11:45	HUN-SOP	WHS
SOP WHS0008	Returning of Material	4	HUN-WHS-Release	16/10/2024 11:48	16/10/2024 11:48	HUN-SOP	WHS
SOP WHS0009	Dispatching Goods	3	HUN-WHS-Release	16/10/2024 11:59	16/10/2024 11:59	HUN-SOP	WHS
SOP WHS0010	Returned and Finished Products Handling	3	HUN-WHS-Release	16/10/2024 12:02	16/10/2024 12:02	HUN-SOP	WHS
SOP WHS0011	Pallet Control	2	HUN-WHS-Release	16/10/2024 12:06	16/10/2024 12:06	HUN-SOP	WHS
SOP WHS0012	Temperature Recording of Warehouse	3	HUN-WHS-Release	16/10/2024 12:10	16/10/2024 12:10	HUN-SOP	WHS
SOP WHS0013	Cleaning And Maintenance of Materials Handling Equipment.	2	HUN-WHS-Release	16/10/2024 12:16	16/10/2024 12:16	HUN-SOP	WHS
SOP WHS0014	Non-Conforming Material Handling	2	HUN-WHS-Release	16/10/2024 12:19	16/10/2024 12:19	HUN-SOP	WHS
SOP WHS0015	Loading and Unloading of Shipping Container	1	HUN-WHS-Release	16/10/2024 12:23	16/10/2024 12:23	HUN-SOP	WHS
SOP WHS0016	Sampling Room Cleaning	1	HUN-WHS-Release	16/10/2024 12:27	16/10/2024 12:27	HUN-SOP	WHS
SOP WHS0017	Handling of Ethanol	1	HUN-WHS-Release	16/10/2024 12:30	16/10/2024 12:30	HUN-SOP	WHS

Master List							
SOP Number	**Title**	**Revision**	**Vault**	**Release Date**	**Effective Date**	**InfoCard Type**	**Department**
SOP PR0001	Occupational Health and Safety	2	HUN-ADMIN-Release	5/11/2021	5/11/2021	HUN-SOP	ADM
SOP PR0002	Sick Leave	2	HUN-ADMIN-Release	5/11/2021	5/11/2021	HUN-SOP	ADM
SOP PR0003	Emergency Evacuation Procedure	2	HUN-ADMIN-Release	5/11/2021	5/11/2021	HUN-SOP	ADM
SOP PR0004	Induction Training - New Employees	3	HUN-ADMIN-Release	5/11/2021	5/11/2021	HUN-SOP	ADM
SOP PR0005	First Aid	2	HUN-ADMIN-Release	5/11/2021	5/11/2021	HUN-SOP	ADM
SOP PR0006	Injury Management Procedure	2	HUN-ADMIN-Release	5/11/2021	5/11/2021	HUN-SOP	ADM
SOP PR0007	Personal Hygiene	3	HUN-ADMIN-Release	19/01/2023	19/01/2023	HUN-SOP	ADM
SOP PR0008	Harassment & Bullying Within Workplace	2	HUN-ADMIN-Release	5/11/2021	5/11/2021	HUN-SOP	ADM
SOP PR0009	Handling of Dangerous Goods	2	HUN-ADMIN-Release	5/11/2021	5/11/2021	HUN-SOP	ADM
SOP PR0010	Security and Removal of Company Property	2	HUN-ADMIN-Release	5/11/2021	5/11/2021	HUN-SOP	ADM
SOP PR0011	Wearing Jewellery and Cosmetics in Work Place	3	HUN-ADMIN-Release	19/01/2023	19/01/2023	HUN-SOP	ADM
SOP PR0012	Glass/brittle Material Breakage Policy	2	HUN-ADMIN-Release	18/03/2025	18/03/2025	HUN-SOP	ADM
SOP PR0013	Gowning Procedure	3	HUN-ADMIN-Release	8/04/2021	8/04/2021	HUN-SOP	ADM
SOP ENG0001	Preventative Maintenance Policy	2	HUN-ENG-Release	17/12/2021	17/12/2021	HUN-SOP	ENG
SOP ENG0002	Engineering Project Management	2	HUN-ENG-Release	17/12/2021	17/12/2021	HUN-SOP	ENG
SOP ENG0003	Contractor Management System	3	HUN-ENG-Release	31/01/2023	31/01/2023	HUN-SOP	ENG
SOP ENG0004	Machine transfer Between Non-Clean Room and Clean Room Area	1	HUN-ENG-Release	17/12/2021	17/12/2021	HUN-SOP	ENG
SOP ENG0005	Safe and Effective Operations of the Compressed Air	1	HUN-ENG-Release	17/12/2021	17/12/2021	HUN-SOP	ENG
SOP ENG0006	Lockout Tag Out (L.O.T.O) Procedure	1	HUN-ENG-Release	12/09/2022	12/09/2022	HUN-SOP	ENG
SOP ENG0007	Tooling Punch Inspection Kit	1	HUN-ENG-Release	3/04/2023	3/04/2023	HUN-SOP	ENG
SOP ENG0008	Tooling Punch Polishing Kit	1	HUN-ENG-Release	3/04/2023	3/04/2023	HUN-SOP	ENG
SOP ENG0009	MSOP for freezer	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0010	MSOP for vaccume freeze dryer	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0011	MSOP for cooking machine	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0012	MSOP for CIP tank	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0013	MSOP For Air compressor	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0014	MSOP For Aeration Machine	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0015	MSOP for DEPOSITOR machine	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0016	MSOP for AIR SHOWER	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0017	MSOP For water filter	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0018	MSOP for heat exchanger	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0020	MSOP for metal seperator	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0021	MSOP for sachet machine	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0022	MSOP for yamato checkweigher	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0023	MSOP for metal detector	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0025	MSOP for buffer tank	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0026	MSOP for cool room	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0027	MSOP for flow wrapper	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0028	MSOP for A & D Checkweigher	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0029	MSOP for Metal seperator 2	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0030	MSOP for 3M Adjustable Case Sealer	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0031	MSOP for Mobile CIP Machine	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0032	MSOP For Shield Allegro XRAY Machine	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0034	MSOP for labelling machine FD	2	HUN-ENG-Release	11/09/2023	11/09/2023	HUN-SOP	ENG
SOP ENG0037	MSOP for Milk Powder Filling Machine	2	HUN-ENG-Release	11/09/2023	11/09/2023	HUN-SOP	ENG
SOP ENG0040	MSOP for Labelling Machine	2	HUN-ENG-Release	11/09/2023	11/09/2023	HUN-SOP	ENG
SOP ENG0041	MSOP for Shield Solo Xray Machine	2	HUN-ENG-Release	11/09/2023	11/09/2023	HUN-SOP	ENG
SOP ENG0042	MSOP for Smart Induction Sealer	2	HUN-ENG-Release	11/09/2023	11/09/2023	HUN-SOP	ENG
SOP ENG0043	MSOP for Sifter Machine	2	HUN-ENG-Release	11/09/2023	11/09/2023	HUN-SOP	ENG
SOP ENG0044	MSOP for Powder Liquid mixer	2	HUN-ENG-Release	11/09/2023	11/09/2023	HUN-SOP	ENG
SOP ENG0045	MSOP for Videojet 1620 Inkjet Coder	2	HUN-ENG-Release	11/09/2023	11/09/2023	HUN-SOP	ENG
SOP ENG0046	MSOP for Dry Powder Blender	2	HUN-ENG-Release	11/09/2023	11/09/2023	HUN-SOP	ENG
SOP ENG0047	MSOP for Joyo Can Seamer	2	HUN-ENG-Release	11/09/2023	11/09/2023	HUN-SOP	ENG
SOP ENG0048	MSOP for Vacuum System for Powder Line	2	HUN-ENG-Release	11/09/2023	11/09/2023	HUN-SOP	ENG
SOP ENG0049	MSOP for Vacuum Conveyer FD	2	HUN-ENG-Release	11/09/2023	11/09/2023	HUN-SOP	ENG
SOP ENG0050	MSOP for Washing Machine FD	2	HUN-ENG-Release	11/09/2023	11/09/2023	HUN-SOP	ENG
SOP ENG0051	MSOP for IRE Mixer FD	2	HUN-ENG-Release	11/09/2023	11/09/2023	HUN-SOP	ENG
SOP ENG0052	MSOP for S-5010EU-BX Flow Wrapper	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0053	MSOP for Vacuum Freeze Dryer 2	2	HUN-ENG-Release	14/06/2024	14/06/2024	HUN-SOP	ENG
SOP ENG0053	MSOP for Vacuum Freeze Dryer 2	1	HUN-ENG-Release	6/11/2020	6/11/2020	HUN-SOP	ENG
SOP ENG0054	MSOP for Checkweigher 2	1	HUN-ENG-Release	16/12/2020	16/12/2020	HUN-SOP	ENG
SOP ENG0054	MSOP for Checkweigher 2	2	HUN-ENG-Release	14/06/2024	14/06/2024	HUN-SOP	ENG
SOP ENG0055	MSOP for Flow wrapper-3	1	HUN-ENG-Release	20/05/2022	20/05/2022	HUN-SOP	ENG
SOP ENG0056	MSOP for Vertical Sealing Machine	2	HUN-ENG-Release	14/06/2024	14/06/2024	HUN-SOP	ENG
SOP ENG0056	MSOP for Vertical Sealing Machine	1	HUN-ENG-Release	28/02/2023	28/02/2023	HUN-SOP	ENG
SOP ENG0057	MSOP for HVAC	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0058	MSOP for Water cooled chiller 1 and 2	2	HUN-ENG-Release	23/01/2023	23/01/2023	HUN-SOP	ENG
SOP ENG0059	MSOP for RO WATER SYSTEM	2	HUN-ENG-Release	17/01/2022	17/01/2022	HUN-SOP	ENG
SOP ENG0060	MSOP for Lab HVAC	2	HUN-ENG-Release	11/09/2023	11/09/2023	HUN-SOP	ENG
SOP ENG0061	MSOP for Sampling room HVAC	2	HUN-ENG-Release	11/09/2023	11/09/2023	HUN-SOP	ENG
SOP ENG0063	MSOP for Powder line HVAC	2	HUN-ENG-Release	11/09/2023	11/09/2023	HUN-SOP	ENG
SOP ENG0065	MSOP for Tablet Press	2	HUN-ENG-Release	13/12/2023	13/12/2023	HUN-SOP	ENG
SOP ENG0066	MSOP for Metal Detector	2	HUN-ENG-Release	13/12/2023	13/12/2023	HUN-SOP	ENG
SOP ENG0067	MSOP for tablet deduster	2	HUN-ENG-Release	13/12/2023	13/12/2023	HUN-SOP	ENG
SOP ENG0068	MSOP for Tablet Hardness Tester	2	HUN-ENG-Release	13/12/2023	13/12/2023	HUN-SOP	ENG
SOP ENG0069	MSOP for Friability Test Machine	2	HUN-ENG-Release	13/12/2023	13/12/2023	HUN-SOP	ENG
SOP ENG0070	MSOP for Disintegration Test Machine	2	HUN-ENG-Release	13/12/2023	13/12/2023	HUN-SOP	ENG
SOP ENG0071	MSOP for Weighing Balance	2	HUN-ENG-Release	11/09/2023	11/09/2023	HUN-SOP	ENG
SOP ENG0072	MSOP for Automatic Coating Machine	1	HUN-ENG-Release	6/01/2022	6/01/2022	HUN-SOP	ENG
SOP ENG0073	MSOP For Wet Granulation Machine - FBD	1	HUN-ENG-Release	23/02/2022	23/02/2022	HUN-SOP	ENG
SOP ENG0074	MSOP For Wet Granulation Machine - RMG	1	HUN-ENG-Release	23/02/2022	23/02/2022	HUN-SOP	ENG
SOP ENG0075	MSOP For Wet Granulation Machine - DCM	1	HUN-ENG-Release	23/02/2022	23/02/2022	HUN-SOP	ENG
SOP ENG0076	MSOP For Wet Granulation Machine - WIP	1	HUN-ENG-Release	23/02/2022	23/02/2022	HUN-SOP	ENG
SOP ENG0077	MSOP For Capsule Filling Machine	1	HUN-ENG-Release	22/03/2022	22/03/2022	HUN-SOP	ENG
SOP ENG0078	MSOP for YHA-Portable Blender	1	HUN-ENG-Release	1/06/2022	1/06/2022	HUN-SOP	ENG
SOP ENG0079	MSOP forPortable Liquid Mixer	1	HUN-ENG-Release	21/10/2022	21/10/2022	HUN-SOP	ENG
SOP ENG0080	MSOP forP130S Tablet Press Machine	1	HUN-ENG-Release	21/10/2022	21/10/2022	HUN-SOP	ENG
SOP ENG0081	MSOP forPG26 Rotary Tablet press machine	1	HUN-ENG-Release	29/03/2023	29/03/2023	HUN-SOP	ENG
SOP ENG0082	MSOP forTablet counting machine	1	HUN-ENG-Release	24/04/2023	24/04/2023	HUN-SOP	ENG
SOP ENG0083	MSOP for Semi -auto capping machine	1	HUN-ENG-Release	5/05/2023	5/05/2023	HUN-SOP	ENG
SOP ENG0084	MSOP for square bottle labelling machine	1	HUN-ENG-Release	3/07/2023	3/07/2023	HUN-SOP	ENG
SOP ENG0085	MSOP for high speed tablet counting machine	1	HUN-ENG-Release	28/07/2023	28/07/2023	HUN-SOP	ENG
SOP ENG0086	MSOP for Shark bottle capping machine	1	HUN-ENG-Release	29/09/2023	29/09/2023	HUN-SOP	ENG
SOP ENG0087	MSOP for BP600AR Shrink Wrapper	1	HUN-ENG-Release	1/11/2023	1/11/2023	HUN-SOP	ENG
SOP ENG0088	MSOP for 3M Case sealer Dry area	1	HUN-ENG-Release	14/11/2023	14/11/2023	HUN-SOP	ENG
SOP ENG0089	MSOP For Vacuum Conveyer Dry Area	1	HUN-ENG-Release	18/12/2023	18/12/2023	HUN-SOP	ENG
SOP ENG0090	MSOP for Tablet HVAC	1	HUN-ENG-Release	23/12/2020	23/12/2020	HUN-SOP	ENG
SOP ENG0091	MSOP for Steam Boiler	1	HUN-ENG-Release	14/06/2024	14/06/2024	HUN-SOP	ENG
SOP ENG0091	MSOP for Steam Boiler	2	HUN-ENG-Release	14/06/2024	14/06/2024	HUN-SOP	ENG
SOP ENG0092	MSOP FOR Tablet manufacturing facility	1	HUN-ENG-Release	19/11/2021	19/11/2021	HUN-SOP	ENG
SOP ENG0093	MSOP for Tablet Manufacturing HVAC	1	HUN-ENG-Release	24/11/2021	24/11/2021	HUN-SOP	ENG
SOP ENG0094	MSOP For Sachet Line HVAC	1	HUN-ENG-Release	26/07/2021	26/07/2021	HUN-SOP	ENG
SOP ENG0094	MSOP For Sachet Line HVAC	2	HUN-ENG-Release	4/07/2024	4/07/2024	HUN-SOP	ENG
SOP ENG0095	MSOP for Sachet Room Facilities	2	HUN-ENG-Release	4/07/2024	4/07/2024	HUN-SOP	ENG
SOP ENG0095	MSOP for Sachet Room Facilities	1	HUN-ENG-Release	28/07/2021	28/07/2021	HUN-SOP	ENG
SOP ENG0096	MSOP For Dust Collector	1	HUN-ENG-Release	22/06/2021	22/06/2021	HUN-SOP	ENG
SOP ENG0096	MSOP For Dust Collector	2	HUN-ENG-Release	17/06/2024	17/06/2024	HUN-SOP	ENG
SOP ENG0097	MSOP for Powder Can Facility	1	HUN-ENG-Release	19/11/2021	19/11/2021	HUN-SOP	ENG
SOP ENG0098	MSOP For Powder Can Packing HVAC	1	HUN-ENG-Release	24/11/2021	24/11/2021	HUN-SOP	ENG
SOP ENG0099	MSOP for Joyo Can Seamer 2	2	HUN-ENG-Release	13/12/2023	13/12/2023	HUN-SOP	ENG
SOP ENG0100	MSOP for YHA Blender	2	HUN-ENG-Release	13/12/2023	13/12/2023	HUN-SOP	ENG
SOP ENG0101	MSOP for Single Stick Machine	1	HUN-ENG-Release	3/05/2021	3/05/2021	HUN-SOP	ENG
SOP ENG0102	MSOP for Cellowrap Machine	2	HUN-ENG-Release	17/06/2024	17/06/2024	HUN-SOP	ENG
SOP ENG0102	MSOP for Cellowrap Machine	1	HUN-ENG-Release	21/06/2021	21/06/2021	HUN-SOP	ENG
SOP ENG0103	MSOP for Vibrating Sieve-1	2	HUN-ENG-Release	17/06/2024	17/06/2024	HUN-SOP	ENG
SOP ENG0103	MSOP for Vibrating Sieve-1	1	HUN-ENG-Release	24/06/2021	24/06/2021	HUN-SOP	ENG
SOP ENG0104	MSOP for Vibrating Sieve-2	2	HUN-ENG-Release	17/06/2024	17/06/2024	HUN-SOP	ENG

SOP ENG0104	MSOP for Vibrating Sieve-2	1	HUN-ENG-Release	24/06/2021	24/06/2021	HUN-SOP	ENG
SOP ENG0105	MSOP for 8 Lane sachet-1	1	HUN-ENG-Release	14/10/2021	14/10/2021	HUN-SOP	ENG
SOP ENG0106	MSOP for Anritsu XR75 Series X-Ray sachet-1	2	HUN-ENG-Release	4/07/2024	4/07/2024	HUN-SOP	ENG
SOP ENG0106	MSOP for Anritsu XR75 Series X-Ray sachet-1	1	HUN-ENG-Release	26/07/2021	26/07/2021	HUN-SOP	ENG
SOP ENG0107	MSOP for Baoli JB Series Milling Machine	1	HUN-ENG-Release	28/07/2021	28/07/2021	HUN-SOP	ENG
SOP ENG0107	MSOP for Baoli JB Series Milling Machine	2	HUN-ENG-Release	4/07/2024	4/07/2024	HUN-SOP	ENG
SOP ENG0108	MSOP for Jiangnan JFZ Grinding Machine	1	HUN-ENG-Release	28/07/2021	28/07/2021	HUN-SOP	ENG
SOP ENG0108	MSOP for Jiangnan JFZ Grinding Machine	2	HUN-ENG-Release	4/07/2024	4/07/2024	HUN-SOP	ENG
SOP ENG0110	MSOP for 12 Lane Sachet Machine-Automation	1	HUN-ENG-Release	21/09/2021	21/09/2021	HUN-SOP	ENG
SOP ENG0111	MSOP for Eiahe Pouch Machine	1	HUN-ENG-Release	14/10/2021	14/10/2021	HUN-SOP	ENG
SOP ENG0112	MSOP for 8 Lane sachet-1	1	HUN-ENG-Release	14/10/2021	14/10/2021	HUN-SOP	ENG
SOP ENG0113	MSOP For Mobile CIP Machine	1	HUN-ENG-Release	13/10/2022	13/10/2022	HUN-SOP	ENG
SOP ENG0114	MSOP For Fitzpatrick milling machine	1	HUN-ENG-Release	1/03/2023	1/03/2023	HUN-SOP	ENG
SOP ENG0115	MSOP For Shrink wrap machine	1	HUN-ENG-Release	1/03/2023	1/03/2023	HUN-SOP	ENG
SOP MIC0001	CLEANING AND MAINTENANCE OF THE MICROBIOLOGY LABORATORY	2	HUN-MIC-Release	25/08/2023	25/08/2023	HUN-SOP	MIC
SOP MIC0002	CLEANING AND CHEMICAL SPILLAGES IN THE MICROBIOLOGY LABORATORY	2	HUN-MIC-Release	28/11/2022	28/11/2022	HUN-SOP	MIC
SOP MIC0003	PERSONAL HEALTH HYGIENE AND SAFETY IN THE MICROBIOLOGY LABORATORY	3	HUN-MIC-Release	18/08/2023	18/08/2023	HUN-SOP	MIC
SOP MIC0004	OPERATION OF THE SAFETY SHOWER AND EYEWASH IN THE MICRO LAB	2	HUN-MIC-Release	19/11/2022	19/11/2022	HUN-SOP	MIC
SOP MIC0005	LONE WORKER ALARM	2	HUN-MIC-Release	16/01/2023	16/01/2023	HUN-SOP	MIC
SOP MIC0006	THE GRAM STAIN	2	HUN-MIC-Release	20/11/2022	20/11/2022	HUN-SOP	MIC
SOP MIC0007	QUALITY CONTROL REQUIREMENTS OF MICROBIOLOGICAL MEDIA, REAGENTS AND DILUENTS	3	HUN-MIC-Release	25/11/2021	25/11/2021	HUN-SOP	MIC
SOP MIC0008	DETERMINATION OF EXPIRY DATE FOR SOLID AND LIQUID MEDIA	2	HUN-MIC-Release	22/11/2022	22/11/2022	HUN-SOP	MIC
SOP MIC0009	ENUMERATION OF BILE TOLERANT GRAM NEGATIVE BACTERIA (BP)	2	HUN-MIC-Release	7/03/2025	7/03/2025	HUN-SOP	MIC
SOP MIC0010	DETERMINATION OF PRESENCE OR ABSENCE OF SALMONELLA SAPP	4	HUN-MIC-Release	7/03/2025	7/03/2025	HUN-SOP	MIC
SOP MIC0011	DETERMINATION OF PRESENCE OR ABSENCE OF E.COLI	3	HUN-MIC-Release	7/03/2025	7/03/2025	HUN-SOP	MIC
SOP MIC0012	OPERATION OF THE INTEGRA DOSE IT P910 PERISTALIC PUMP	2	HUN-MIC-Release	16/01/2024	16/01/2024	HUN-SOP	MIC
SOP MIC0013	IDENTIFICATIOPN OF MICROORGANISMS BY API KIT	2	HUN-MIC-Release	10/03/2023	10/03/2023	HUN-SOP	MIC
SOP MIC0014	PRELIMINARY FOR THE IDENTIFICATION OF MICROORGANISMS	2	HUN-MIC-Release	10/03/2023	10/03/2023	HUN-SOP	MIC
SOP MIC0015	BACTISTAPH LATEX AGGLUTINATION TEST KIT	2	HUN-MIC-Release	10/03/2023	10/03/2023	HUN-SOP	MIC
SOP MIC0016	TOTAL VIABLE MESOPHILIC COUNT BACTERIA YEAST AND FUNGI	4	HUN-MIC-Release	7/03/2025	7/03/2025	HUN-SOP	MIC
SOP MIC0017	OPERATION OF THE MAS 100NT MICROBIAL AIR SAMPLER	2	HUN-MIC-Release	18/01/2024	18/01/2024	HUN-SOP	MIC
SOP MIC0018	ENUMERATION OF STERIKON BIOLOGICAL INDICATOR AMPOULES	2	HUN-MIC-Release	18/03/2023	18/03/2023	HUN-SOP	MIC
SOP MIC0019	PREPARATION AND MAINTENANCE OF THE CULTURE COLLECTION	2	HUN-MIC-Release	17/03/2021	17/03/2021	HUN-SOP	MIC
SOP MIC0019	PREPARATION AND MAINTENANCE OF THE CULTURE COLLECTION	3	HUN-MIC-Release	16/04/2024	16/04/2024	HUN-SOP	MIC
SOP MIC0020	IDENTIFICATION OF SPORES FROM TAPE LIFTS	2	HUN-MIC-Release	18/03/2023	18/03/2023	HUN-SOP	MIC
SOP MIC0021	VALIDATION OF PRODUCTS	2	HUN-MIC-Release	5/05/2021	5/05/2021	HUN-SOP	MIC
SOP MIC0021	VALIDATION OF PRODUCTS	3	HUN-MIC-Release	15/06/2024	15/06/2024	HUN-SOP	MIC
SOP MIC0022	DETERMINATION OF PRESENCE OR ABSENCE OF SALMONELLA SPP.	2	HUN-MIC-Release	18/03/2023	18/03/2023	HUN-SOP	MIC
SOP MIC0023	DETERMINATION OF PRESENCE OR ABSENCE OF S. AURES BP	3	HUN-MIC-Release	6/09/2021	6/09/2021	HUN-SOP	MIC
SOP MIC0024	WASTE MANAGEMENT PROCEDURE FOR THE MICRO LAB	2	HUN-MIC-Release	2/12/2022	2/12/2022	HUN-SOP	MIC
SOP MIC0025	DETERMINATION OF PRESENCE OR ABSENCE OF PS. AERUGINOSA BP	2	HUN-MIC-Release	28/02/2024	28/02/2024	HUN-SOP	MIC
SOP MIC0026	OPERATION OF THE PINNACLE LABORATORY FREEZER	2	HUN-MIC-Release	22/02/2024	22/02/2024	HUN-SOP	MIC
SOP MIC0027	OPERATION OF THE LUTRON TM 947SD FOUR CHANNEL DATA LOGGER	2	HUN-MIC-Release	16/01/2023	16/01/2023	HUN-SOP	MIC
SOP MIC0028	OPERATION OF THE DIGITECH XC0424 DATA LOGGER	2	HUN-MIC-Release	15/01/2023	15/01/2023	HUN-SOP	MIC
SOP MIC0029	TEMPERATURE MAPPING OF EQUIPMENT IN THE MICRO LAB	2	HUN-MIC-Release	25/01/2023	25/01/2023	HUN-SOP	MIC
SOP MIC0030	MONITORING AND MAINTENANCE OF INCUBATORS AND REFRIGERATORS	2	HUN-MIC-Release	2/12/2022	2/12/2022	HUN-SOP	MIC
SOP MIC0031	OPERATION AND CALIBRATION OF LABORATORY TIMERS	3	HUN-MIC-Release	6/02/2024	6/02/2024	HUN-SOP	MIC
SOP MIC0032	OPERATION AND VERIFICATION OF MICROPIPETTES	3	HUN-MIC-Release	16/02/2024	16/02/2024	HUN-SOP	MIC
SOP MIC0033	CALIBARTAION OF ANALOGUE THERMOMETERS	2	HUN-MIC-Release	8/12/2022	8/12/2022	HUN-SOP	MIC
SOP MIC0034	OPERATION OF GILSON MACROMAN	2	HUN-MIC-Release	8/12/2022	8/12/2022	HUN-SOP	MIC
SOP MIC0035	OPERATION OF THE ZEISS PRIMOSTAR MICROSCOPE	2	HUN-MIC-Release	8/12/2022	8/12/2022	HUN-SOP	MIC
SOP MIC0036	OPERATION AND CALIBRATION OF THE METTLER ML3002T AND ML5002T BALANCES	2	HUN-MIC-Release	15/12/2022	15/12/2022	HUN-SOP	MIC
SOP MIC0037	OPERATION OF THE DENSICHECK PLUS NEPHELOMETER	2	HUN-MIC-Release	30/01/2024	30/01/2024	HUN-SOP	MIC
SOP MIC0038	OPERATION AND CALIBRATION OF THE METTLER ML204T BALANCE	2	HUN-MIC-Release	15/12/2022	15/12/2022	HUN-SOP	MIC
SOP MIC0039	OPERATION OF THE METTLER RS-P25 PRINTER	2	HUN-MIC-Release	15/12/2022	15/12/2022	HUN-SOP	MIC
SOP MIC0040	OPERATION OF THE CILMAREC HOTPLATE STIRRER	2	HUN-MIC-Release	15/02/2023	15/02/2023	HUN-SOP	MIC
SOP MIC0041	OPERATION OF THE THERMOLINE TWB-24D WATERBATH	1	HUN-MIC-Release	21/02/2020	21/02/2020	HUN-SOP	MIC
SOP MIC0042	OPERATION OF THE SEWARD 400 STOMACHER	2	HUN-MIC-Release	15/02/2023	15/02/2023	HUN-SOP	MIC
SOP MIC0043	OPERATION OF HERATHERM INCUBATORS AND DRYER	2	HUN-MIC-Release	20/01/2023	20/01/2023	HUN-SOP	MIC
SOP MIC0044	OPERATION AND MAINTENANCE OF THE ELIX 3 ADVANTAGE 3 WATER SYSTEM	2	HUN-MIC-Release	15/02/2023	15/02/2023	HUN-SOP	MIC
SOP MIC0045	OPERATION AND MAINTENANCE OF THE ULTRASAFE SERIES CLASS II BIOLOGICAL SAFETY CABINET	2	HUN-MIC-Release	25/03/2023	25/03/2023	HUN-SOP	MIC
SOP MIC0046	OPERATION OF THE STUART SC6+ COLONY COUNTER	2	HUN-MIC-Release	25/01/2023	25/01/2023	HUN-SOP	MIC
SOP MIC0047	OPERATION AND CALIBRATION OF THE CYBER JERBOA CEC5513 ATHERTON AUTOCLAVE	2	HUN-MIC-Release	25/08/2023	25/08/2023	HUN-SOP	MIC
SOP MIC0048	CALIBRATION USE AND MAINTENANCE OF THE OAKTON PH 700 METER	2	HUN-MIC-Release	20/02/2023	20/02/2023	HUN-SOP	MIC
SOP MIC0049	OPERATION AND MAINTENANCE OF THE HWS 120 LAMINAR FLOW CABINET	2	HUN-MIC-Release	25/01/2023	25/01/2023	HUN-SOP	MIC
SOP MIC0050	OPERATION OF THE COLE PARMER VARIABLE SPEED VORTEX MIXER	2	HUN-MIC-Release	25/02/2023	25/02/2023	HUN-SOP	MIC
SOP MIC0051	OPERATION OF THE COLE PARMER ULTRASONIC CLEANER	2	HUN-MIC-Release	15/02/2023	15/02/2023	HUN-SOP	MIC
SOP MIC0052	OPERATION OF THE AVERY DENNISON MONARCH 1136 LABEL GUN	2	HUN-MIC-Release	20/02/2023	20/02/2023	HUN-SOP	MIC
SOP MIC0053	OPERATION OF THE MY TEMP MINI DIGITAL INCUBATOR	2	HUN-MIC-Release	25/08/2023	25/08/2023	HUN-SOP	MIC
SOP MIC0054	QUALITY RISK ASSESSMENT IN THE MICROBIOLOGY LABORATORY	2	HUN-MIC-Release	25/01/2023	25/01/2023	HUN-SOP	MIC
SOP MIC0055	MICRO LAB INVESTIGATION REPORT VER002	3	HUN-MIC-Release	26/01/2024	26/01/2024	HUN-SOP	MIC
SOP MIC0056	INTERNAL AUDIT PROCEDURES FOR THE MICROBIOLOGY LABORATORY	2	HUN-MIC-Release	25/11/2022	25/11/2022	HUN-SOP	MIC
SOP MIC0057	GOOD DOCUMENTATION POLICY AND DATA INTEGRITY	2	HUN-MIC-Release	25/01/2023	25/01/2023	HUN-SOP	MIC
SOP MIC0058	MANAGEMENT OF THE MICROBIOLOGY CALIBRATION SYSTEM	2	HUN-MIC-Release	15/12/2022	15/12/2022	HUN-SOP	MIC
SOP MIC0059	MICROBIOLOGY QUALITY MANUAL	2	HUN-MIC-Release	25/11/2022	25/11/2022	HUN-SOP	MIC
SOP MIC0060	BALANCE USE CALIBRATION AND MAINTENANCE	2	HUN-MIC-Release	15/12/2022	15/12/2022	HUN-SOP	MIC
SOP MIC0061	GENERATION AND EXECUTION OF INSTALLATION OPERATIONAL AND PERFORMANCE QUALIFICATION PROTOCOLS AND REPORTS	2	HUN-MIC-Release	20/12/2022	20/12/2022	HUN-SOP	MIC
SOP MIC0062	QUALIFICATION DEVIATION MANAGEMENT MICRO VALIDATION STUDIES	2	HUN-MIC-Release	25/01/2023	25/01/2023	HUN-SOP	MIC
SOP MIC0063	COMPUTER USE POLICY	2	HUN-MIC-Release	25/02/2023	25/02/2023	HUN-SOP	MIC
SOP MIC0064	TRAINING STAFF IN THE MICRO LAB	3	HUN-MIC-Release	19/01/2024	19/01/2024	HUN-SOP	MIC
SOP MIC0065	RECEIPT AND REGISTRATION OF SAMPLE IN THE MICRO LAB	3	HUN-MIC-Release	8/07/2024	8/07/2024	HUN-SOP	MIC
SOP MIC0065	RECEIPT AND REGISTRATION OF SAMPLE IN THE MICRO LAB	2	HUN-MIC-Release	2/07/2021	2/07/2021	HUN-SOP	MIC
SOP MIC0066	ISSUING A CERTIFICATE OF ANALYSIS	3	HUN-MIC-Release	21/03/2024	21/03/2024	HUN-SOP	MIC
SOP MIC0066	ISSUING A CERTIFICATE OF ANALYSIS	2	HUN-MIC-Release	12/03/2021	12/03/2021	HUN-SOP	MIC
SOP MIC0067	LABORATORY NOTEBOOK POLICY	2	HUN-MIC-Release	25/02/2023	25/02/2023	HUN-SOP	MIC
SOP MIC0068	ISSUACE USAGE AND CONTROL OF BOUND BOOKS	2	HUN-MIC-Release	25/01/2023	25/01/2023	HUN-SOP	MIC
SOP MIC0069	ENVIRONMENTAL MONITORING	2	HUN-MIC-Release	3/11/2021	3/11/2021	HUN-SOP	MIC
SOP MIC0070	PREPARATION AND CONTROL OF STANDARD OPERATING PROCEDURE	2	HUN-MIC-Release	26/02/2024	26/02/2024	HUN-SOP	MIC
SOP MIC0070	PREPARATION AND CONTROL OF STANDARD OPERATING PROCEDURE	1	HUN-MIC-Release	30/09/2020	30/09/2020	HUN-SOP	MIC
SOP MIC0071	ENUMERATION PF COLIFORM GB	2	HUN-MIC-Release	6/09/2021	6/09/2021	HUN-SOP	MIC
SOP MIC0072	OPERSTION OF THE SENTINO FILTER DISPENSER	2	HUN-MIC-Release	26/02/2024	26/02/2024	HUN-SOP	MIC
SOP MIC0073	OPERATION OF THE PALL LABORATORY MANIFOLD	2	HUN-MIC-Release	14/02/2024	14/02/2024	HUN-SOP	MIC
SOP MIC0074	EXAMINATION OF PROCESS WATER BY MEMBRANE FILTRATION	3	HUN-MIC-Release	15/09/2021	15/09/2021	HUN-SOP	MIC
SOP PRD0001	Freezer and freeze dryer SOP	4	HUN-PRD-Release	8/12/2023	8/12/2023	HUN-SOP	PRD
SOP PRD0002	Material Dispensary	4	HUN-PRD-Release	18/07/2023	18/07/2023	HUN-SOP	PRD
SOP PRD0003	Cooking Machine SOP	3	HUN-PRD-Release	9/01/2024	9/01/2024	HUN-SOP	PRD
SOP PRD0004	Heat Exchanger	2	HUN-PRD-Release	9/01/2024	9/01/2024	HUN-SOP	PRD
SOP PRD0005	Aeration Machine Operation	1	HUN-PRD-Release	18/07/2019	18/07/2019	HUN-SOP	PRD
SOP PRD0006	Depositor Machine Opearation	1	HUN-PRD-Release	18/07/2019	18/07/2019	HUN-SOP	PRD
SOP PRD0007	De-molding, Sorting and Bulk Packing	2	HUN-PRD-Release	24/08/2023	24/08/2023	HUN-SOP	PRD
SOP PRD0008	Heat Sealer Operation	2	HUN-PRD-Release	24/11/2023	24/11/2023	HUN-SOP	PRD
SOP PRD0009	Start up and operation of x-ray inspection machine	3	HUN-PRD-Release	19/01/2024	19/01/2024	HUN-SOP	PRD
SOP PRD0010	Mold and tray wash using ultra sonic machine	1	HUN-PRD-Release	18/07/2019	18/07/2019	HUN-SOP	PRD
SOP PRD0011	Leak-Test Machine	3	HUN-PRD-Release	19/09/2023	19/09/2023	HUN-SOP	PRD
SOP PRD0013	General Cleaning	4	HUN-PRD-Release	23/06/2022	23/06/2022	HUN-SOP	PRD
SOP PRD0014	Freezer and freeze dryer Cleaning	1	HUN-PRD-Release	24/08/2023	24/08/2023	HUN-SOP	PRD
SOP PRD0015	SOP for A&D Checkweigher	2	HUN-PRD-Release	31/08/2023	31/08/2023	HUN-SOP	PRD
SOP PRD0017	SOP For SLE-64040 RO Water System Sanitisation	2	HUN-PRD-Release	21/04/2021	21/04/2021	HUN-SOP	PRD
SOP PRD0018	Bulk and Packed Product Storage	1	HUN-PRD-Release	24/08/2023	24/08/2023	HUN-SOP	PRD
SOP PRD0019	Portable CIP Machine Procedure	1	HUN-PRD-Release	25/02/2020	25/02/2020	HUN-SOP	PRD
SOP PRD0020	SLE-64040 RO Water System Operation	3	HUN-PRD-Release	31/08/2023	31/08/2023	HUN-SOP	PRD
SOP PRD0021	Shield Allegro Xray Machine	2	HUN-PRD-Release	5/08/2020	5/08/2020	HUN-SOP	PRD
SOP PRD0022	800 L Stirrer operation	2	HUN-PRD-Release	18/09/2023	18/09/2023	HUN-SOP	PRD
SOP PRD0023	Labelling Machine Operation	1	HUN-PRD-Release	24/08/2023	24/08/2023	HUN-SOP	PRD
SOP PRD0024	Sifter Machine	1	HUN-PRD-Release	30/06/2020	30/06/2020	HUN-SOP	PRD
SOP PRD0025	Powder Liquid Mixer	1	HUN-PRD-Release	17/07/2020	17/07/2020	HUN-SOP	PRD
SOP PRD0026	Dry Powder Blender	1	HUN-PRD-Release	17/08/2020	17/08/2020	HUN-SOP	PRD
SOP PRD0027	Washing Machine SOP	2	HUN-PRD-Release	12/09/2024	12/09/2024	HUN-SOP	PRD
SOP PRD0028	IRE Mixer SOP	1	HUN-PRD-Release	24/09/2020	24/09/2020	HUN-SOP	PRD

SOP PRD0029	Freeze Dryer 2 SOP	1	HUN-PRD-Release	13/11/2020	13/11/2020	HUN-SOP	PRD
SOP PRD0030	Production Line Start-up and Clearance	1	HUN-PRD-Release	30/12/2020	30/12/2020	HUN-SOP	PRD
SOP PRD0031	SOP for OMORI S-5010EU-BX Flow Wrapper	1	HUN-PRD-Release	17/07/2020	17/07/2020	HUN-SOP	PRD
SOP PRD0032	FD Checkweigher 2 SOP	2	HUN-PRD-Release	11/01/2021	11/01/2021	HUN-SOP	PRD
SOP CL0001	Cleaning of Offices/Lunch Room/Windows/Doors and Floors	2	HUN-PRD-Release	19/01/2024	19/01/2024	HUN-SOP	CL
SOP PRD0033	Flowrapper 3	1	HUN-PRD-Release	20/06/2022	20/06/2022	HUN-SOP	PRD
SOP PRD0035	Tablet Press Sejong MRC-30N	2	HUN-PRD-Release	20/02/2025	20/02/2025	HUN-SOP	PRD
SOP PRD0036	Operation and Cleaning of Metal Detector	3	HUN-PRD-Release	10/03/2025	10/03/2025	HUN-SOP	PRD
SOP CL0002	Cleaning Requirements for the Male & Female Amenities	2	HUN-PRD-Release	19/01/2024	19/01/2024	HUN-SOP	CL
SOP CL0003	Cleaning of washbay and dry storage room	3	HUN-PRD-Release	17/02/2023	17/02/2023	HUN-SOP	CL
SOP PRD0037	Operation and Cleaning Procedure for Tablet Deduster	2	HUN-PRD-Release	10/03/2025	10/03/2025	HUN-SOP	PRD
SOP PRD0038	Electro Lab Hardness Tester EHT-5PR	2	HUN-PRD-Release	10/03/2025	10/03/2025	HUN-SOP	PRD
SOP CL0004	Approved Cleaning Chemicals Agents	4	HUN-PRD-Release	25/03/2022	25/03/2022	HUN-SOP	CL
SOP PRD0039	Operation and Cleaning procedure of Friability Test Machine	2	HUN-PRD-Release	10/03/2025	10/03/2025	HUN-SOP	PRD
SOP PRD0040	Operation and Cleaning Procedure of Disintegration Machine	2	HUN-PRD-Release	10/03/2025	10/03/2025	HUN-SOP	PRD
SOP PRD0041	Operation and Cleaning Procedure of Weighing Balance	2	HUN-PRD-Release	10/03/2025	10/03/2025	HUN-SOP	PRD
SOP PRD0042	The Operating and Cleaning Procedre of Russell Sieving Machine	2	HUN-PRD-Release	13/05/2022	13/05/2022	HUN-SOP	PRD
SOP PRD0043	The Operating and Cleaning Procedre of Sejong Coating Machine	2	HUN-PRD-Release	27/05/2022	27/05/2022	HUN-SOP	PRD
SOP PRD0044	Operation and Cleaning of Anish Fluid Bed (AFB) Dryer	2	HUN-PRD-Release	5/07/2023	5/07/2023	HUN-SOP	PRD
SOP PRD0045	Operation and Cleaning of Rapid Mixture Granulator (RMG) Machine	2	HUN-PRD-Release	13/05/2022	13/05/2022	HUN-SOP	PRD
SOP PRD0046	The Cleaning and Opration Procedure of Automatic Encapsulation (NJP series)	1	HUN-PRD-Release	24/04/2022	24/04/2022	HUN-SOP	PRD
SOP PRD0047	General Cleaning - Tablet Line	2	HUN-PRD-Release	22/08/2022	22/08/2022	HUN-SOP	PRD
SOP PRD0048	Operation of YHA-2A Blender	1	HUN-PRD-Release	27/04/2022	27/04/2022	HUN-SOP	PRD
SOP PRD0049	Operation and cleaning Procedure Of YHA Portable Dry Powder Blender (Model: WHJ-100)	1	HUN-PRD-Release	19/07/2023	19/07/2023	HUN-SOP	PRD
SOP PRD0053	Operation and cleaning of Tablet counting machine	1	HUN-PRD-Release	20/06/2023	20/06/2023	HUN-SOP	PRD
SOP PRD0054	Operation and cleaning of Semi-auto capping machine	1	HUN-PRD-Release	20/06/2023	20/06/2023	HUN-SOP	PRD
SOP PRD0055	Operation and Cleaning Procedure for Tablet Counting and Filling Machine	1	HUN-PRD-Release	21/08/2023	21/08/2023	HUN-SOP	PRD
SOP PRD0056	Operation and Cleaning of Labelling Machine (Square Bottle) (CAL830,831,832)	1	HUN-PRD-Release	21/08/2023	21/08/2023	HUN-SOP	PRD
SOP PRD0057	Operation and Cleaning of Shark Capping machine	1	HUN-PRD-Release	22/03/2024	22/03/2024	HUN-SOP	PRD
SOP PRD0058	Operation and Cleaning of BP600AR Shrink Wrapper	1	HUN-PRD-Release	22/03/2024	22/03/2024	HUN-SOP	PRD
SOP PRD0060	Handling of Ethanol in Production Area	1	HUN-PRD-Release	21/02/2024	21/02/2024	HUN-SOP	PRD
SOP PRD0062	Packing Line Start-up and Clearance	2	HUN-PRD-Release	26/06/2023	26/06/2023	HUN-SOP	PRD
SOP PRD0063	Milk Powder Filling Machine	1	HUN-PRD-Release	28/05/2020	28/05/2020	HUN-SOP	PRD
SOP PRD0064	Induction sealer Operation	2	HUN-PRD-Release	24/11/2023	24/11/2023	HUN-SOP	PRD
SOP PRD0065	Videojet 1620 coder	1	HUN-PRD-Release	4/06/2020	4/06/2020	HUN-SOP	PRD
SOP PRD0066	SMART Sealing Machine Operation	1	HUN-PRD-Release	22/06/2020	22/06/2020	HUN-SOP	PRD
SOP PRD0068	3M Case Sealer	1	HUN-PRD-Release	30/06/2020	30/06/2020	HUN-SOP	PRD
SOP PRD0069	Joyo Can Seamer Operation	1	HUN-PRD-Release	12/08/2020	12/08/2020	HUN-SOP	PRD
SOP PRD0070	Vacuum System For Milk Powder Line	1	HUN-PRD-Release	14/08/2020	14/08/2020	HUN-SOP	PRD
SOP PRD0071	Joyo Can Seamer 2	1	HUN-PRD-Release	17/02/2021	17/02/2021	HUN-SOP	PRD
SOP PRD0072	SOP For YHA Blender	1	HUN-PRD-Release	1/02/2021	1/02/2021	HUN-SOP	PRD
SOP PRD0073	Operation and Cleaning of FVC-1 Vacuum Conveyor	1	HUN-PRD-Release	17/06/2021	17/06/2021	HUN-SOP	PRD
SOP PRD0074	Operation and Cleaning of Automatic L-sealer Wrapping Machine	1	HUN-PRD-Release	1/12/2023	1/12/2023	HUN-SOP	PRD
SOP PRD0075	SOP for Single Stick Machine	1	HUN-PRD-Release	3/05/2021	3/05/2021	HUN-SOP	PRD
SOP PRD0076	General Cleaning - Sachet Line	1	HUN-PRD-Release	13/07/2021	13/07/2021	HUN-SOP	PRD
SOP PRD0077	Operation of Yihua YHA-2A Blender	1	HUN-PRD-Release	13/07/2021	13/07/2021	HUN-SOP	PRD
SOP PRD0078	Inspection and operation of sieve and mesh	2	HUN-PRD-Release	13/05/2022	13/05/2022	HUN-SOP	PRD
SOP PRD0079	Operation and Cleaning of Grinding Machine	2	HUN-PRD-Release	19/06/2023	19/06/2023	HUN-SOP	PRD
SOP PRD0080	Operation and Cleaning of Milling Machine	1	HUN-PRD-Release	10/08/2021	10/08/2021	HUN-SOP	PRD
SOP PRD0081	Operation and Cleaning of 12-Lane Machine	2	HUN-PRD-Release	28/02/2022	28/02/2022	HUN-SOP	PRD
SOP PRD0082	Operation and Checking of X-Ray Machine	1	HUN-PRD-Release	16/08/2021	16/08/2021	HUN-SOP	PRD
SOP PRD0084	Operation and Cleaning of KNS-500/5 8-Lane Machine	1	HUN-PRD-Release	14/03/2022	14/03/2022	HUN-SOP	PRD
SOP CL0005	Cleaning of mops, buckets, brooms, brushes & related cleaning equipment	1	HUN-PRD-Release	14/03/2024	14/03/2024	HUN-SOP	CL
SOP CL0006	Use of cleaning status tags and room logs	3	HUN-PRD-Release	24/05/2024	24/05/2024	HUN-SOP	CL
SOP PRD0086	Operation of Leak Test Machine	2	HUN-PRD-Release	10/08/2023	10/08/2023	HUN-SOP	PRD
SOP PRD0089	Handling Probiotics	1	HUN-PRD-Release	14/09/2022	14/09/2022	HUN-SOP	PRD
SOP PRD0094	Operation and Cleaning Procedure for Shark Line Capping Machine	1	HUN-PRD-Release	22/03/2024	22/03/2024	HUN-SOP	PRD
SOP PRD0095	OPERATION AND CLEANING PROCEDURE OF SHARK SHRINK MACHINE (CAL593)	1	HUN-PRD-Release	22/04/2024	22/04/2024	HUN-SOP	PRD
SOP QA0001	Document Control	8	HUN-QA-Release	14/10/2024	14/10/2024	HUN-SOP	QA
SOP QA0002	Good Manufacturing Practice	3	HUN-QA-Release	9/03/2023	9/03/2023	HUN-SOP	QA
SOP QA0003	Guidelines for Preparing GMP Agreement	2	HUN-QA-Release	24/10/2022	24/10/2022	HUN-SOP	QA
SOP QA0004	Training Program	5	HUN-QA-Release	14/10/2024	14/10/2024	HUN-SOP	QA
SOP QA0005	Change Control Procedure	5	HUN-QA-Release	17/02/2023	17/02/2023	HUN-SOP	QA
SOP QA0006	Quality Incident/ Deviation Procedure	3	HUN-QA-Release	26/07/2024	26/07/2024	HUN-SOP	QA
SOP QA0007	Quality Risk Management	3	HUN-QA-Release	30/06/2022	30/06/2022	HUN-SOP	QA
SOP QA0008	Internal Audit	6	HUN-QA-Release	1/11/2024	1/11/2024	HUN-SOP	QA
SOP QA0009	Calibration Procedure	3	HUN-QA-Release	27/05/2022	27/05/2022	HUN-SOP	QA
SOP QA0010	Recall Procedure	7	HUN-QA-Release	9/12/2024	9/12/2024	HUN-SOP	QA
SOP QA0011	Pest Control	3	HUN-QA-Release	27/09/2022	27/09/2022	HUN-SOP	QA
SOP QA0012	Reject Items Procedure	3	HUN-QA-Release	22/04/2024	22/04/2024	HUN-SOP	QA
SOP QA0013	Customer Complaints Management	4	HUN-QA-Release	12/12/2024	12/12/2024	HUN-SOP	QA
SOP QA0014	Water Quality Monitoring	6	HUN-QA-Release	6/07/2023	6/07/2023	HUN-SOP	QA
SOP QA0015	Management Meetings	3	HUN-QA-Release	23/04/2024	23/04/2024	HUN-SOP	QA
SOP QA0016	Registers	3	HUN-QA-Release	24/06/2022	24/06/2022	HUN-SOP	QA
SOP QA0017	New Product Introduction	3	HUN-QA-Release	11/12/2024	11/12/2024	HUN-SOP	QA
SOP QA0018	Environmental Monitoring Procedure	8	HUN-QA-Release	8/08/2022	8/08/2022	HUN-SOP	QA
SOP QA0019	Receiving and Dispatching Export Dairy Goods	5	HUN-QA-Release	23/04/2024	23/04/2024	HUN-SOP	QA
SOP QA0020	Label Requirements for Export Dairy Goods	3	HUN-QA-Release	18/07/2023	18/07/2023	HUN-SOP	QA
SOP QA0021	Sampling and Testing of Export Dairy Goods	3	HUN-QA-Release	22/04/2024	22/04/2024	HUN-SOP	QA
SOP QA0022	GMP Control of Pre-Printed Labels & Pre-Printed Packaging Components	4	HUN-QA-Release	5/12/2023	5/12/2023	HUN-SOP	QA
SOP QA0023	Out Of Specification Procedure (OOS)	2	HUN-QA-Release	23/11/2022	23/11/2022	HUN-SOP	QA
SOP QA0024	Rework Procedure	4	HUN-QA-Release	9/12/2024	9/12/2024	HUN-SOP	QA
SOP QA0025	Returned Goods Procedure	3	HUN-QA-Release	18/01/2024	18/01/2024	HUN-SOP	QA
SOP QA0026	Supplier/ Manufacturer QualificationApproval Procedure	5	HUN-QA-Release	25/07/2023	25/07/2023	HUN-SOP	QA
SOP QA0028	Product Quality Review	4	HUN-QA-Release	4/12/2024	4/12/2024	HUN-SOP	QA
SOP QA0029	Release For Finish Product	3	HUN-QA-Release	23/04/2024	23/04/2024	HUN-SOP	QA
SOP QA0030	Operation and Calibration of Water Activity Meter	2	HUN-QA-Release	21/10/2022	21/10/2022	HUN-SOP	QA
SOP QA0031	Operation of Hygiena Ensure Touch	3	HUN-QA-Release	22/04/2024	22/04/2024	HUN-SOP	QA
SOP QA0032	Calibration/ Performance Check of Scales	2	HUN-QA-Release	27/05/2022	27/05/2022	HUN-SOP	QA
SOP QA0033	Operation and Calibration of Moisture Balance	3	HUN-QA-Release	22/04/2024	22/04/2024	HUN-SOP	QA
SOP QA0034	Label Requirements for Use	6	HUN-QA-Release	7/12/2021	16/01/2023	HUN-SOP	QA
SOP QA0035	Data Integrity and Security	1	HUN-QA-Release	26/10/2022	26/10/2023	HUN-SOP	QA
SOP QA0036	Batch Register	1	HUN-QA-Release	31/10/2022	31/10/2022	HUN-SOP	QA
SOP QA0037	In-process Checks	2	HUN-QA-Release	29/08/2022	29/08/2022	HUN-SOP	QA
SOP QA0038	Sampling, Testing, Releasing and Retention of Raw Material	4	HUN-QA-Release	4/12/2024	4/12/2024	HUN-SOP	QA
SOP QA0039	Corrective and Preventive Action (CAPA)	3	HUN-QA-Release	20/01/2023	20/01/2023	HUN-SOP	QA
SOP QA0040	Use and handling of MWO & PWO	2	HUN-QA-Release	21/04/2022	21/04/2022	HUN-SOP	QA
SOP QA0041	Reconciliation	3	HUN-QA-Release	26/07/2024	26/07/2024	HUN-SOP	QA
SOP QA0042	Stability Studies Procedure	3	HUN-QA-Release	12/12/2024	12/12/2024	HUN-SOP	QA
SOP QA0043	Handling of Retest/Expired Extension of Raw Material	2	HUN-QA-Release	17/01/2023	17/01/2023	HUN-SOP	QA
SOP QA0044	Monitoring of Purified Water	4	HUN-QA-Release	17/05/2022	17/05/2022	HUN-SOP	QA
SOP QA0045	Vistor Management	2	HUN-QA-Release	23/04/2024	23/04/2024	HUN-SOP	QA
SOP QA0046	Code Creation Procedure	2	HUN-QA-Release	12/12/2024	12/12/2024	HUN-SOP	QA
SOP QA0047	Operation and Calibration of Label Counter	2	HUN-QA-Release	5/12/2024	5/12/2024	HUN-SOP	QA
SOP QA0048	Taste and Colour Testing Procedure	2	HUN-QA-Release	2/08/2024	2/08/2024	HUN-SOP	QA
SOP QA0049	Control of Tablet Machine Tooling	1	HUN-QA-Release	7/12/2022	7/12/2022	HUN-SOP	QA
SOP QA0051	Halal Manual	3	HUN-QA-Release	17/10/2024	17/10/2024	HUN-SOP	QA
SOP QA0052	Rotational Testing of Bulk Products and Finished Products	1	HUN-QA-Release	16/08/2023	16/08/2023	HUN-SOP	QA
SOP QC0001	Preparation and Control of Standard Operating Procedures	2	HUN-QC-Release	6/02/2023	6/02/2023	HUN-SOP	QC
SOP QC0002	Laboratory Good Documentation Practices and Data integrity	2	HUN-QC-Release	7/02/2023	7/02/2023	HUN-SOP	QC
SOP QC0003	Good Laboratory Practices	2	HUN-QC-Release	7/02/2023	7/02/2023	HUN-SOP	QC
SOP QC0004	Issuance usage and control of bound books	2	HUN-QC-Release	7/02/2023	7/02/2023	HUN-SOP	QC
SOP QC0005	Document Issue and Results Reporting	4	HUN-QC-Release	6/02/2023	6/02/2023	HUN-SOP	QC
SOP QC0006	Employee induction and training Record Procedure	2	HUN-QC-Release	19/06/2023	19/06/2023	HUN-SOP	QC
SOP QC0007	Preparation and Control of Analytical Test Procedure and Analytical Test worksheet	3	HUN-QC-Release	8/02/2023	8/02/2023	HUN-SOP	QC
SOP QC0008	Review of Pharmacopeia Update	2	HUN-QC-Release	8/02/2023	8/02/2023	HUN-SOP	QC
SOP QC0009	Equipments usage and Calibration Requirements	2	HUN-QC-Release	8/02/2023	8/02/2023	HUN-SOP	QC
SOP QC0010	Instrument Repair and Maintenance	3	HUN-QC-Release	28/08/2023	28/08/2023	HUN-SOP	QC
SOP QC0011	Laboraoty computer systems and software management	2	HUN-QC-Release	19/06/2023	19/06/2023	HUN-SOP	QC

SOP QC0012	Validation and usage of Excel calculation Worksheet	2	HUN-QC-Release	9/02/2023	9/02/2023	HUN-SOP	QC
SOP QC0013	Handling of Laboratory Standards	2	HUN-QC-Release	28/04/2022	28/04/2022	HUN-SOP	QC
SOP QC0014	Review of Analytical Document	2	HUN-QC-Release	9/02/2023	9/02/2023	HUN-SOP	QC
SOP QC0015	Receipt and Handling of QC Samples (Raw Material, Finished Products, Analytical Request)	2	HUN-QC-Release	9/02/2023	9/02/2023	HUN-SOP	QC
SOP QC0016	Responsibilities of Quality Control Department	2	HUN-QC-Release	9/02/2023	9/02/2023	HUN-SOP	QC
SOP QC0017	Good Chromatography Practices	3	HUN-QC-Release	28/08/2023	28/08/2023	HUN-SOP	QC
SOP QC0018	Handing of Out of Specification (OOS) Laboratory Result	3	HUN-QC-Release	7/09/2022	7/09/2022	HUN-SOP	QC
SOP QC0019	Laboratory Incidents	2	HUN-QC-Release	10/02/2023	10/02/2023	HUN-SOP	QC
SOP QC0020	Validation Master Plan-Quality Control Department	2	HUN-QC-Release	10/02/2023	10/02/2023	HUN-SOP	QC
SOP QC0021	Validation of Analytical Methods	2	HUN-QC-Release	28/04/2022	28/04/2022	HUN-SOP	QC
SOP QC0022	Analytical Method Transfer	2	HUN-QC-Release	10/02/2023	10/02/2023	HUN-SOP	QC
SOP QC0024	Laboratory Safety	2	HUN-QC-Release	10/02/2023	10/02/2023	HUN-SOP	QC
SOP QC0025	Dangerous Goods Handing and Storage	2	HUN-QC-Release	13/02/2023	13/02/2023	HUN-SOP	QC
SOP QC0026	Handling of Laboratory Chemicals	3	HUN-QC-Release	28/08/2023	28/08/2023	HUN-SOP	QC
SOP QC0027	Handling Laboratory Glassware	2	HUN-QC-Release	13/02/2023	13/02/2023	HUN-SOP	QC
SOP QC0028	Glassware Washup	2	HUN-QC-Release	13/02/2023	13/02/2023	HUN-SOP	QC
SOP QC0029	Timer Calibration	2	HUN-QC-Release	14/02/2023	14/02/2023	HUN-SOP	QC
SOP QC0030	Handling of Third party and Special request analysis	2	HUN-QC-Release	14/02/2023	14/02/2023	HUN-SOP	QC
SOP QC0031	Analyst Qualification	2	HUN-QC-Release	14/02/2023	14/02/2023	HUN-SOP	QC
SOP QC0032	Operation and calibration of Balance	2	HUN-QC-Release	14/02/2023	14/02/2023	HUN-SOP	QC
SOP QC0033	Operation, Maintenance and Calibration of Ultrasonic Bath	2	HUN-QC-Release	19/06/2023	19/06/2023	HUN-SOP	QC
SOP QC0034	Operation, Maintenance and Calibration of Dry Bath	2	HUN-QC-Release	14/02/2023	14/02/2023	HUN-SOP	QC
SOP QC0035	Operation, Maintenance and Calibration of Micropipettes	2	HUN-QC-Release	14/02/2023	14/02/2023	HUN-SOP	QC
SOP QC0036	Operation and Calibration of Drying oven -Heratherm OMS 180	2	HUN-QC-Release	15/02/2023	15/02/2023	HUN-SOP	QC
SOP QC0037	Operation and Maintenance of UHPLC	3	HUN-QC-Release	6/03/2024	6/03/2024	HUN-SOP	QC
SOP QC0038	Operation and Maintenance of Gas Chromatography	2	HUN-QC-Release	6/03/2024	6/03/2024	HUN-SOP	QC
SOP QC0039	Basic Operation and Maintenance of Inductively Coupled Plasma Optical Emission Spectrometer	3	HUN-QC-Release	6/03/2024	6/03/2024	HUN-SOP	QC
SOP QC0040	Installation and Maintenance of Gas Cylinder	2	HUN-QC-Release	19/06/2023	19/06/2023	HUN-SOP	QC
SOP QC0041	Operation and Maintenance of Dynaflow Fume Cupboard	2	HUN-QC-Release	20/06/2023	20/06/2023	HUN-SOP	QC
SOP QC0042	Laboratory Notebook	2	HUN-QC-Release	15/02/2023	15/02/2023	HUN-SOP	QC
SOP QC0043	Audit of Contract Laboratory	2	HUN-QC-Release	15/02/2023	15/02/2023	HUN-SOP	QC
SOP QC0044	Contract Testing	2	HUN-QC-Release	15/02/2023	15/02/2023	HUN-SOP	QC
SOP QC0045	Validation Life cycle management of Laboratory Equipments	2	HUN-QC-Release	28/04/2022	28/04/2022	HUN-SOP	QC
SOP QC0046	Operation of the Eppendorf Centrifuge	2	HUN-QC-Release	20/06/2023	20/06/2023	HUN-SOP	QC
SOP QC0047	Operation and Calibration of the Polarimeter	2	HUN-QC-Release	20/06/2023	20/06/2023	HUN-SOP	QC
SOP QC0048	Operation and Calibration of Disintegration test apparatus	1	HUN-QC-Release	18/05/2020	18/05/2020	HUN-SOP	QC
SOP QC0049	Operation and Calibration of Sieve Shaker	2	HUN-QC-Release	20/06/2023	20/06/2023	HUN-SOP	QC
SOP QC0050	Operation and Calibration of Brookfield Viscometer	2	HUN-QC-Release	22/06/2023	22/06/2023	HUN-SOP	QC
SOP QC0051	Operation and Calibration of Refractive Index apparatus	2	HUN-QC-Release	22/06/2023	22/06/2023	HUN-SOP	QC
SOP QC0052	Operation and Calibration of Melting Point apparatus	2	HUN-QC-Release	22/06/2023	22/06/2023	HUN-SOP	QC
SOP QC0053	Operation and Maintenance of Laboratory Water Purification System	2	HUN-QC-Release	22/06/2023	22/06/2023	HUN-SOP	QC
SOP QC0054	Operation of EC 2000 Gardner Kit	2	HUN-QC-Release	22/06/2023	22/06/2023	HUN-SOP	QC
SOP QC0055	Operation and Calibration of Mettler Toledo V10S KF Titrator	2	HUN-QC-Release	22/06/2023	22/06/2023	HUN-SOP	QC
SOP QC0056	Operation and Calibration of Mettler Toledo G20S Compact Titrator	2	HUN-QC-Release	26/06/2023	26/06/2023	HUN-SOP	QC
SOP QC0057	Operation and Maintenance of Scorched Particles Apparatus (ADPI)	2	HUN-QC-Release	26/06/2023	26/06/2023	HUN-SOP	QC
SOP QC0058	Operation and Calibration of Vacuum oven-Labec VO3	1	HUN-QC-Release	18/05/2020	18/05/2020	HUN-SOP	QC
SOP QC0059	Operation and Calibration of Muffle furnace	2	HUN-QC-Release	26/06/2023	26/06/2023	HUN-SOP	QC
SOP QC0060	Operation and Calibration of Agilent Cary 60 UV-Visible spectrophotometer	2	HUN-QC-Release	26/06/2023	26/06/2023	HUN-SOP	QC
SOP QC0061	Operation and Calibration of Agilent Cary 630 FTIR	2	HUN-QC-Release	26/06/2023	26/06/2023	HUN-SOP	QC
SOP QC0062	Operation and Calibration of Orion Star A211 pH meter	2	HUN-QC-Release	26/06/2023	26/06/2023	HUN-SOP	QC
SOP QC0063	Operation and Calibration of Orion Star A112 Conductivity Meter	2	HUN-QC-Release	26/06/2023	26/06/2023	HUN-SOP	QC
SOP QC0064	Operation, Maintenance and Calibration of Water Bath	2	HUN-QC-Release	26/06/2023	26/06/2023	HUN-SOP	QC
SOP QC0065	Operation of AMP Gas Detector	2	HUN-QC-Release	26/06/2023	26/06/2023	HUN-SOP	QC
SOP QC0066	HW-SOP-QC-0066-V001-Operation and Calibration of Water Activity meter	1	HUN-QC-Release	3/05/2022	3/05/2022	HUN-SOP	QC
SOP QC0067	HW-SOP-QC-0067-V001-Operation and Calibration of High-Performance Thin Layer Chromatography Systems	1	HUN-QC-Release	19/05/2022	19/05/2022	HUN-SOP	QC
SOP QC0068	HW-SOP-QC-0068-V001-Operation and User Management of Agilent Open Lab Software	1	HUN-QC-Release	16/05/2023	16/05/2023	HUN-SOP	QC
SOP QC0073	Operation and Maintenance of Laboratory Fridge & Freezer	1	HUN-QC-Release	28/01/2025	28/01/2025	HUN-SOP	QC
SOP VAL0001	Validation Master Plan	5	HUN-VAL-Release	16/05/2022	16/05/2022	HUN-SOP	VAL
SOP VAL0002	Installation and Operational Qualification Protocol	2	HUN-VAL-Release	2/03/2023	2/03/2023	HUN-SOP	VAL
SOP VAL0003	Validation Process	2	HUN-VAL-Release	2/03/2023	2/03/2023	HUN-SOP	VAL
SOP VAL0004	Computerised System Validation Master Plan	2	HUN-VAL-Release	24/06/2022	24/06/2022	HUN-SOP	VAL
SOP WHS0001	WAREHOUSE STAFF ORIENTATION	2	HUN-WHS-Release	16/10/2024	16/10/2024	HUN-SOP	WHS
SOP WHS0002	RECEIVING ITEMS	4	HUN-WHS-Release	16/10/2024	16/10/2024	HUN-SOP	WHS
SOP WHS0003	Sampling Result Sheet	3	HUN-WHS-Release	16/10/2024	16/10/2024	HUN-SOP	WHS
SOP WHS0004	Goods Receivable Register	2	HUN-WHS-Release	16/10/2024	16/10/2024	HUN-SOP	WHS
SOP WHS0005	Warehouse Designated Areas	3	HUN-WHS-Release	16/10/2024	16/10/2024	HUN-SOP	WHS
SOP WHS0006	Stock Movements In Warehouse	4	HUN-WHS-Release	16/10/2024	16/10/2024	HUN-SOP	WHS
SOP WHS0007	Material Requisition and Picking	4	HUN-WHS-Release	16/10/2024	16/10/2024	HUN-SOP	WHS
SOP WHS0008	Returning of Material	4	HUN-WHS-Release	16/10/2024	16/10/2024	HUN-SOP	WHS
SOP WHS0009	Dispatching Goods	3	HUN-WHS-Release	16/10/2024	16/10/2024	HUN-SOP	WHS
SOP WHS0010	Returned and Finished Products Handling	3	HUN-WHS-Release	16/10/2024	16/10/2024	HUN-SOP	WHS
SOP WHS0011	Pallet Control	2	HUN-WHS-Release	16/10/2024	16/10/2024	HUN-SOP	WHS
SOP WHS0012	Temperature Recording of Warehouse	3	HUN-WHS-Release	16/10/2024	16/10/2024	HUN-SOP	WHS
SOP WHS0013	Cleaning And Maintenance of Materials Handling Equipment.	2	HUN-WHS-Release	16/10/2024	16/10/2024	HUN-SOP	WHS
SOP WHS0014	Non-Conforming Material Handling	2	HUN-WHS-Release	16/10/2024	16/10/2024	HUN-SOP	WHS
SOP WHS0015	Loading and Unloading of Shipping Container	1	HUN-WHS-Release	16/10/2024	16/10/2024	HUN-SOP	WHS
SOP WHS0016	Sampling Room Cleaning	1	HUN-WHS-Release	16/10/2024	16/10/2024	HUN-SOP	WHS
SOP WHS0017	Handling of Ethanol	1	HUN-WHS-Release	16/10/2024	16/10/2024	HUN-SOP	WHS

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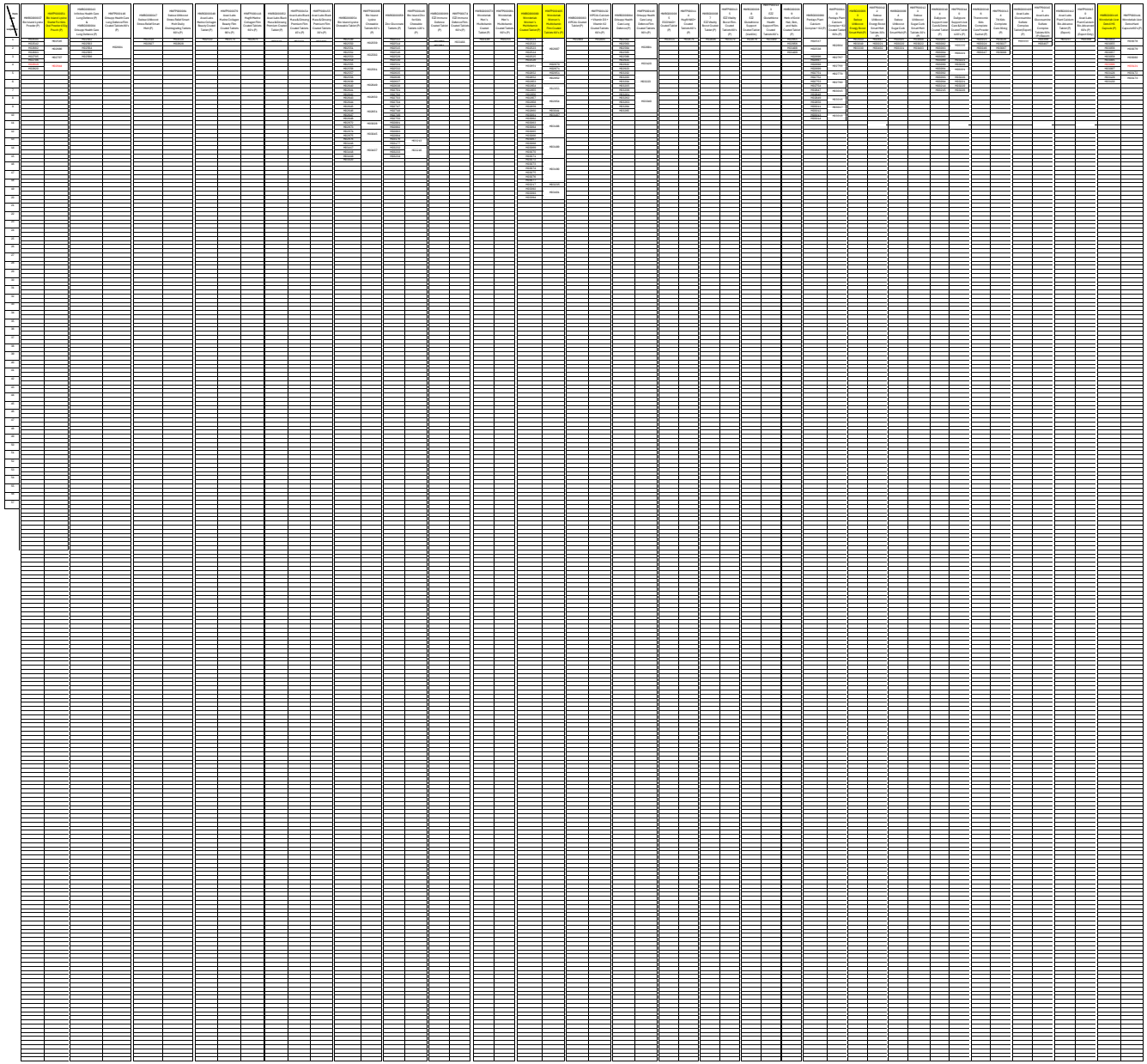

Change Control Number	Details of Proposed Change	Code Number	Raised by	Impact level	Risk Level	Date Raised	Close date	Comments
		May-22						
CC22019	TGA Audit	SOP PTB0009; SOP PTB0009 SOP PPW0004; SOP QA0018; SOP QA0032; SOP QA0044 QAF019; QAF020; QAF021; QAF085; QAF086; QAF087; QAF088,SOP QA0005, SOP VAL0004	s22	Major	Low	13/05/2022	4/07/2022	Closed
CC22020	New UHPLC in QC lab	NA		Major	Low	11/05/2022	19/05/2023	Closed
CC22023	Alliaus sachet project	RM Spec and sample results sheet HWRM000181 to 186,188 and 189, BG spec HWBG000033 to 35, MWO HWBG000033 to 35, PM Spec and sample results sheet HWPP000030 to 38 and HWPC000069, FP spec HWFP000047 to 49, PWO HWFP000047 to 49		Major	Low	20/05/2022	8/08/2022	Closed
		Jun-22						
CC22027	Document updated.	SOP PFD013, PRF009, HWRM000029 Specification, SOP QA0007, QAF006	s22	Major	Low	14/06/2022	29/07/2022	Closed
CC22031	New SOP for Flow Wrappers 3	SOP PFD0033		Major	Low	20/06/2022	20/06/2022	Closed
CC22032	New SOP for YHA portable blender (WHJ-100)	SOP PTB 0015		Major	Low	20/06/2022	20/07/2023	Closed
CC22035	Infinitus Project Transfer from GW	HWRM000191 to HWRM000228 (except HWRM000217)		Major	Low	23/06/2022	4/11/2022	Closed
CC22036	New SOP Control of Tablet Machine Tooling / Sub change control linked to CC21065 / Register Tablet Machine Tooling	SOP QA0049, QAF0092, Tooling Specification		Major	Low	29/06/2022	7/12/2022	Closed
		Jul-22						
CC22039	JBX Lysine Porject Transfer	HWRM000232 / HWRM000233	s22	Major	Low	7/07/2022	23/11/2022	Closed
CC22041	NATA certificate application for micto lab	NA		Major		19/07/2022	25/11/2022	Closed
CC22043	New lab software to replace chromeleon	NA		Major	low	21/07/2022	21/02/2023	Closed
		Aug-22						
CC22050	Dr Nature Sleep & Beauty, Immunity & Lung Project Transfer from GW	HWBG000040, 41	s22	Major	Low	18/08/2022	1/12/2022	Closed
CC22052	New Analytical test methods for Astaxauthin	ATM-0325, ATM-0326		Major	Low	19/08/2022	6/10/2022	Closed
CC22053	Vmores Snap formula update	MWO HWBG000012, PWO HWFP000005, HWFP000005 packaging instruction		Major	Low	24/08/2022	2/09/2022	Closed
CC22055	Alliaus Finish Product spec update	HWFP000047, HWFP000048, HWFP000049 SPEC		Major	Low	31/08/2022	28/02/2023	Closed
		Sep-22						
CC22058	New SOP for handling Probiotics	SOP PPW0015 Handling Probiotics v001	s22	Major	Low	14/09/2022	14/09/2022	Closed
CC22063	New product introduce for EZZ Whitening Tablets(Pharm)	HWRM000308, HWRM00309		Major	Low	15/09/2022	10/07/2023	Closed
		Oct-22						
CC22069	NPD for EZZ Eye Health Chewable Tablets(Pharm)	HWBG000046	s22	Major	Low	5/10/2022	24/10/2023	Closed
CC22071	NPD for Morosil Orange Powder(P)	HWBG000044		Major	Low	13/10/2022	28/09/2023	Closed
CC22072	NPD for Swisse Saffron Tablet(P)	HWRM000269 , HWRM000270		Major	Low	13/10/2022	26/07/2023	Closed
CC22073	New analytical testing procedure for residual solvent by GC	NA		Major	Low	14/10/2022	25/10/2022	Closed
		Nov-22						
CC22083	NPD for Nesfi Collagen and Vitamins Coated Tablet (P)	HWRM000293, HWRM000294, HWRM000295, HWRM000296	s22	Major	Low	3/11/2022	30/06/2023	Closed
CC22084	NPD for Nesfi Black Maca, Vitamin & Mineral Coated Tablet (P)	HWBG000052		Major	Low	4/11/2022	14/04/2023	Closed
CC22085	NPD for Ezz Bone Growth Chewable Tablet(P)	HWBG000048		Major	Low	4/11/2022	8/05/2023	Closed
CC22091	NPD for Dr Nature Vitamin B Tablet	HWBG000057		Major	Low	25/11/2022	26/06/2023	Closed
CC22092	NPD For Dr Nature Hair Skin Nail Tablet	HWBG000055		Major	Low	25/11/2022	27/06/2023	Closed
		Dec-22						
CC22099	NPD for Bio Island Lysine Chewable Tablet (Pharm)	HWRM000302, HWRM000303	s22	Major	Low	5/12/2022	25/09/2023	Closed
CC22104	Monthly Tablet Mezzanine Floor and Ground Floor GMP Inspection Form	QAF095, QAF096		Major	Low	20/12/2022	20/12/2022	Closed
CC22105	NPD for HSG Liver Support Coated Tablet (Pharm) and Calcium VD3 + Magnesium Coated Tablet (Pharm)	HWBG000060		Major	Low	22/12/2022	6/06/2023	Closed

Change Control Number	Details of Proposed Change	Code Number	Raised by	Impact level	Risk Level	Date Raised	Close date	Comments
		Jan-23						
CC23001	Dispensary job to sampling room	NA	s22	Major	Low	3/01/2023	3/01/2023	Closed
CC23007	Perdays 3 tablet projects transfer	HWRM000315, HWRM000316, HWRM000317, HWRM000318, HWRM000319, HWRM000320		Major	Low	23/01/2023	13/12/2023	Closed
		Feb-23						
CC23016	Tablet MWO waste verification update	HWBG000043, HWBG000059	s22	Major	Low	13/02/2023	15/02/2023	Closed
CC23017	NPD for Cemoy NMN 200mg Coated Table (P) and FTJ 888 Immunity Coated Tablet (P)	HWRM000333		Major	Low	15/02/2023		NPD is in process
CC23018	NPD for EZZ TFJ 888 Immunity Coated Tablet (P)	HWRM000326 , HWRM000327, HWRM000328		Major	Low	15/02/2023	15/03/2024	Closed
CC23019	NPD For Cemoy Whitening Coated Tablet (P)			Major	Low	16/02/2023	2/08/2023	Closed
CC23020	NPD for Cemoy Anti Aging Coated Tablet (P)	HWRM000322 , HWRM000323 , HWRM000324 , HWRM000325		Major	Low	16/02/2023	2/08/2023	Closed
CC23021	NPD for Cemoy Eye Support Coated Tablet (P)	HWRM000329, HWRM000330, HWRM000331, HWRM000332		Major	Low	16/02/2023	2/08/2023	Closed
		Mar-23						
CC23026	NPD for Cemoy Hairgro Coated Tablet (P)	HWRM000334	s22	Major	Low	7/03/2023	18/05/2023	Closed
CC23028	Moving in Tablet Compress Machine in Room 3	NA		Major	Low	9/03/2023	15/03/2023	Closed
CC23029	NPD for EZZ Ashwagandha Coated Tablet (P)	HWBG000072		Major	Low	9/03/2023	1/08/2023	Closed
CC23030	Moving the sieving machine into 074 TDR2 Tablet Dispensary Room 2	CAL781		Major	Low	27/03/2023	29/03/2023	Closed
CC23031	NPD for EZZ Phytomin Ca + VD3 & K2 Coated Tablet (P) and EZZ Hair Protector Coated Tablet (P)	HWBG000076, HWBG000077		Major	Low	27/03/2023	30/11/2023	Closed
CC23032	NPD for Wonderlab Men's Multivitamin Coated Tablet(P)	HWRM000340, HWRM000341, HWRM000342, HWRM000343,		Major	Low	29/03/2023	23/10/2023	Closed
		Apr-23						
		May-23						
CC23045	NPD for Ezz Children's Essential Mineral Tablets (P)	HWBG00075	s22	Major	Low	3/05/2023	5/02/2024	Closed
CC23049	NPD for Ezz NA NMN 175,000 mcg Coated Tablet (Export Only) (Pharm)	HWBG000079		Major	Low	30/05/2023	21/11/2023	Closed
		Jun-23						
CC23058	weight, thickness, hardness & the formulation of excipient and coating. Change the amount if HWRM000215, HWRM000218,	Spec of HWBG000061	s22	Major	Low	26/06/2023	27/06/2023	Closed
CC23059	NPD for Wonderlab Women's Multivitamin Tablets	HWBG000080, HWFP000105		Major	Low	26/06/2023	8/12/2023	Closed
		Jul-23						
CC23061	SOP preparation for Halal Manual	SOP QA0051	s22	Major	Low	4/07/2023	1/08/2023	Closed
CC23062	Change the source of Lysine from HWRM000232 to HWRM000344 . Adjust the amount of HWRM000091 and HWRM0000088. Update the limit friability from 1.0% to 2.0%	HWBG000054		Major	Low	7/07/2023	9/11/2023	Closed
CC23067	Document need to update as per Halal Audit observation	SOP QA0051; Version:02; SOPQA0026; Version: 05		Major	Moderate	21/07/2023	28/07/2023	Closed
		Aug-23						
CC23071	SOP of leak Testing Machine need to update	SOP PPW012	s22	Major	Low	4/08/2023	11/08/2023	Closed
CC23074	Update testing method of Lutein	HWBG000068		Major	Low	11/08/2023	11/09/2023	Closed
CC23075	New FP spec for Adevaya Hairgro, Bebright, Neoskin and eyebright bottle packing with label	HWFP000096, HWFP000097, HWFP000098, HWFP000099		Major	Low	14/08/2023	18/08/2024	Closed
CC23081	Update core & coated tablet hardness.Reduce the amount of carnuba wax. Update MI to remove grinding process of silica	HWBG000043		Major	Low	23/08/2023	25/09/2023	Closed
		Sep-23						
CC23090	Raw materials shelf life need to update	HWRM000153,HWRM000152	s22	Major	Low	1/09/2023	29/01/2024	Closed
CC23099	Change humidity requirement from 20% to 40% for zone-2 , AHU-2.2 Z2	Tablet manufacturing Area		Major	Low	20/09/2023	31/09/2023	Closed
CC23101	HWRM000262 spec and sample result sheet update	HWRM000262		Major	Low	20/09/2023	20/09/2023	Closed
CC23103	HWRM000088 spec and sample result sheet update	HWRM000088		Major	Low	20/09/2023	25/09/2023	Closed
CC23107	NPD for Cabemi Calcium K2+nMangnesium Coated Tablet (P)	HWBG000083		Major	Low	29/09/2023	30/07/2024	Closed
		Oct-23						
CC23110	Update Bgspec of HWBG000079 by changing thickness, hardness and RM quantity	HWBG000079	s22	Major	Low	6/10/2023		NPD is in process
CC23111	Change the layout of the room no (085 TBF1)	NA		Major	High	10/10/2023	17/11/2023	Closed
CC23114	Update BG spec of HWBG000047 by updating the amount of HWRM000168 & HWRM000265	HWBG000047		Major	Low	19/10/2023	11/03/2024	Closed
CC23115	Update HWFP000091 spec. Replace HWFP000101 with HWPL000053 and HWPC000113.	HWFP000091		Major	Low	20/10/2023	23/10/2023	Closed
CC23116	Update testing method of Biotin to not assayed, quantified by input	HWBG000080		Major	Low	27/10/2023	27/10/2023	Closed
CC23117	Update IP Specifiction of HWIP000006 to version 02	HWIP000006		Major	Low	30/10/2023	30/10/2023	Closed
		Nov-23						
CC23118	Creation of new BGcode for Orisupp Health Care Lung Defence (P)	HWBG000084	s22	Major	Low	2/11/2023	7/08/2024	Closed
CC23120	NPD EGO NAD+ Coated Tablet (P)	HWBG000085		Major	Low	14/11/2023	30/04/2024	Closed
CC23121	NPD Biobasic NAD+ Coated Tablet (P)	HWBG000087		Major	Low	15/11/2023	5/08/2024	Closed
CC23122	NPD Biobasic Glutathione Support Tablet (P)	HWBG000088		Major	Low	15/11/2023	16/10/2024	Closed
CC23123	NPD EGO Vitamin B Coated Tablet (P)	HWBG000086		Major	Low	15/11/2023	13/03/2024	Closed
CC23126	Update HWFP000093 spec. Add HWPC000136 into packing BOM.Update product name. Update special instructions. Update units per layer and per shipper.	HWFP000093		Major	Low	20/11/2023	20/11/2023	Closed
CC23127	NPD for Herb of Gold Hair, Skin, and Nails Coated tablet (P)	HWBG000089		Major	Low	22/11/2023	19/08/2024	Closed
CC23128	Update assay test of potassium to QBI for EZZ Children's Essential	HWBG000075		Major	Low	22/11/2023	24/11/2023	Closed
CC23130	Labelling and packing procedure for EZZ L-Lysine Growth Hard Capsule 60's (P) from GW site	HWFP000104		Major	Low	27/11/2023		Closed
CC23131	New SOP for BP600AR Shrink Wrapper	SOP PTB0024, SOP PK0013		Major	Low	29/11/2023	22/03/2024	Closed
		Dec-23						
CC23134	RM Spec and sample result sheet	HWRM000200		Major	Low	6/12/2023	6/12/2023	Closed
CC23137	New IP and BG code for Perdays	HWBG000090		Major	Low	13/12/2023	10/07/2024	Closed
CC23140	New form creation for sample submission	QCF063		Major	Low	13/12/2023	4/01/2023	Closed

Change Control Number	Details of Proposed Change	Code Number	Raised by	Impact level	Risk Level	Date Raised	Close date	Comments
			Jan-24					
CC24005	NPD for Swisse Ultiboost Energy Fastmelt (P)	HWBG000093	s22	Major	Low	5/01/2024	12/08/2024	Closed
CC24006	NPD for Swisse Sugarcraving Fastmelt (P)	HWBG000094		Major	Low	5/01/2024	1/08/2024	Closed
CC24015	NPD for QD Detox Sachets	HWBG000099		Major	Low	22/01/2024		BG Spec updated, MWO will be prepared upon order
CC24018	HACCP Plan for Plain and Skim Milk Powder	FSM2.9.1,2,3,4		Major	Low	24/01/2024	24/01/2024	Closed
CC24019	New SOP for Handling of Ethanol	SOP WHS0017, SOP PTB0026		Major	Low	29/01/2024	26/02/2024	Closed
			Feb-24					
CC24025	Update composition of HWRM000390	HWBG000089	s22	Major	Low	7/02/2024	13/08/2024	Closed
CC24026	Request to create RM, label , consumer box, shipper code and all relevent documents and Fpspec for EZZ Sugar Metabolism Hard Capsules 60's (Pharm)	HWFP000112		Major	Low	7/02/2024	16/02/2024	Closed
CC24036	Change product category from export only to listed	HWBG000083		Major	Low	29/02/2024	29/02/2024	Closed
			Mar-24					
CC24039	NPD EZZ Joint Energy Coated Tablet	HWBG000095	s22	Major	Low	6/03/2024	25/11/2024	Closed
CC24045	Update the testing method VB12 to QBI, Update appearance of HWIP000005 to light pink	HWBG0000080, HWIP000005		Major	Low	11/03/2024	18/03/2024	Closed
CC24055	Update BG spec by increasing the amount of magnesium stearate	HWBG000054		Major	Low	19/03/2024	16/04/2024	Closed
CC24056	NPD Eimele Calibrate Red Powder Sachet (P)	HWBG000096		Major	Low	19/03/2024	19/06/2024	Closed
CC24057	RM Sample result sheet and spec need to update by changing the Supplier	HWRM000171, HWRM000233		Major	Low	20/03/2024	20/03/2024	Closed
CC24063	Production new SOP need to prepare	SOP PTB023, SOP PTB024		Major	Low	22/03/2024	28/06/2024	Closed
CC24064	Remove grinding Step of HWRM000249 and HWRM000215	HWBG000080		Major	low	22/03/2024	22/03/2024	Closed
CC24065	SOP QC for Operation and Calibration of Automatic Polarimeter	SOPQC0069		Major	Low	26/03/2024	13/06/2024	Closed
CC24066	EDMS system implementation	NA		Major	Low	26/03/2024	15/10/2024	Closed
CC24067	Update teting method of Iodine and Calcium to QBI	HWBG000075		Major	Low	27/03/2024	2/04/2024	Closed
CC24068	NPD for QD Skin Sheep Placenta coated tablet (P)	HWBG000097		Major	Low	27/03/2024		NPD in progress
CC24069	NPD for QD Men's Vitality Coated Tablet (P)	HWBG000098		Major	Low	27/03/2024		BG Spe, MWO updated
CC24070	NPD for By Health Liver Support Coated Tablet (P)	HWBG000100		Major	Low	28/03/2024		NPD in progress
			Apr-24					
CC24072	Change HWRM000088 to new milk powder source	HWBG000037	s22	Major	Low	3/04/2024	3/05/2024	Closed
CC24073	NPD for Perdays Beauty Collagen Sachets	HWBG000101		Major	Low	3/04/2024		PI, PWO (HWFP000130) pending
CC24074	NPD for Perdays Iron + C Powder Sachet	HWBG000102		Major	Low	3/04/2024		PI, PWO (HWFP000131) pending
CC24075	NPD for Perdays Folate Powder Sachet	HWBG0000		Major	Low	3/04/2024		NPD in progress
CC24076	New PC code is required for HWFP000095	HWFP000095		Major	Low	4/04/2024	8/04/2024	Closed
CC24077	New FP code is required for HWBG000049 Hugfit Marine Collagen Powder	HWFP000118		Major	Low	8/04/2024	30/04/2024	Closed
CC24079	NPD for Bio Island Liver Health Support 50,000 mg Tablet (P)	HWBG000104		Major	Low	9/04/2024	9/12/2024	Closed
CC24080	NPD for Infinitus Sleep Updated Formula	HWBG000105		Major	Low	9/04/2024		Project not started yet
CC24084	Reconciliation update for dry product	HWBG000054		Major	Low	16/04/2024	16/04/2024	Closed
CC24085	Removing titrateble acidity and update protein to protein SNF basis as per supplier specification	HWRM000424, 425		Major	Low	16/04/2024	16/04/2024	Closed
CC24087	NPD ABM TN Kids Tribiotic Multivitamin	HWBG000106		Major	Low	18/04/2024	22/11/2024	Closed
CC24088	Monthly Document Update	SOP QA0012, SOP QA0015, SOP QA0019, SOP QA0021, SOP QA0029, SOP QA0031, SOP QA0033, SOP QA0045		Major	Low	22/04/2024	23/04/2024	Closed
CC24089	Nicotinic Acid Testing method is changed to QBI	HWBG000085		Major	Low	23/04/2024	24/04/2024	Closed
CC24090	Change to water and ethanol coating, Increase HWRM000249 and update thickness limit	HWBG000090		Major	Low	23/04/2024	3/06/2024	Closed
CC24093	Update the BG spec by changing the arsenic limit	HWBG000091		Major	Low	30/04/2024	13/05/2024	Closed
CC24094	Change the overgae of HWRM000293 to 40% & HWRM000274 to 20%	HWBG000049		Major	Low	30/04/2024		Document will update upon order
			May-24					
CC24095	Weighing Balance will transfer from FR room to Sampling Room	CAL827, CAL017	s22	Major	Low	3/05/2024	6/06/2024	Closed
CC24097	Reduce the input of HWRM000286	HWBG000069		Major	Low	6/05/2024	3/07/2024	Closed
CC24108	NPD for Wonderfur Bites- Immune Booster for Dogs	HWBG000107		Major	Low	29/05/2024	17/06/2024	Closed
CC24109	NPD for Wonderfur Bites- Senior support for Dogs	HWBG000108		Major	Low	29/05/2024	17/06/2024	Closed
			Jun-24					
CC24121	NPD NEFSI Advanced Joint Care Coated Tablet	HWBG000109	s22	Major	Low	17/06/2024		FP Spec, PWO pending
CC24123	BG Spec need to update	HWBG000080		Major	Low	18/06/2024	17/07/2024	Closed
CC24129	NPD for By Health Liver Support Plus Coated Tablet (P)	HWBG000110		Major	Low	24/06/2024		NPD in progress
CC24131	Update the appearance statement of the product	HWBG000108		Major	Low	26/06/2024	13/08/2024	Closed
CC24133	Update Manufacturing steps for ARTG by including Release for Supply, Packing and labelling , Secondary Packing	HWBG000047, HWBG000093, HWBG000094		Major	Low	27/06/2024	30/07/2024	Closed
CC24134	update QCsop	SOP QC0032 to V03		Major	Low	28/06/2024	3/07/2024	Closed
CC24136	Site master File need to update	SMF001		Major	Low	28/06/2024	5/07/2024	Closed
			Jul-24					
CC24137	Update Testing method of Sodium Chondrotin sulfate to QBI & add COO and animal part bovine for HWRM000430	HWBG000095	s22	Major	Low	2/07/2024		Document not Updated yet
CC24138	NPD for Perdays Fibre Powder Sachet	HWBG000111		Major	Low	2/07/2024	8/01/2025	Closed

CC24139	Update IP spec by increasing RO water to 100.078 mgand Ethanol 120.00 mg. change grinding screen size to 2.00 mm	HWIP000007	s22	Major	Low	3/07/2024	4/07/2024	Closed
CC24144	NPD for Acaci Labs Nature Calcium Bio-Advance Tablet (P) (Export)	HWBG000112		Major	Low	16/07/2024		RM Spec, PWO pending
CC24147	Desiccannt Machine Installation	TBIQ028, TBOQ029, TBMSOP026,TBPM040, SOP PTB0029		Major	Low	18/07/2024		SOP PTB0029 pending
CC24148	Update HWRM000464 spec to follow current BP method instead of USP	HWRM000464		Major	Low	23/07/2024	25/07/2024	Closed
CC24149	NPD for Wonderfur Bites-Senior Support for Cats	HWBG000113		Major	Low	24/07/2024	2/09/2024	Closed
CC24150	NPD for Wonderfur Bites-Immune Boost for Cats	HWBG000114		Major	Low	24/07/2024	2/09/2024	Closed
CC24151	Update L-proline powder specification and sampling result sheet to follow USP	HWRM000388		Major	Low	25/07/2024	25/07/2024	Closed
CC24152	update the product name and switch HWRM0168 to HWRM0127	HWBG000088		Major	Low	25/07/2024	25/07/2024	Closed
			Aug-24					
CC24156	4 new New data loggers will be introduced	EQC110, EQC111,EQC112,EQC113	s22	Major	Low	1/08/2024	9/08/2024	Closed
CC24158	e BG spec of HWBG000107 by updating the formulation and also update the reference sta	HWBG000107		Major	Low	1/08/2024	13/08/2024	Closed
CC24162	NPD Wonderlab Liver Detox Plus HS Capsule (P)	HWBG000115		Major	Low	8/08/2024		NPD in progress
CC24163	NPD Wonderlab Liver DetoX HS Capsule (P)	HWBG000116		Major	Low	8/08/2024	8/10/2024	Closed
CC24165	Remove upper limit of calcium and magnesium from HWRM000476	HWBG0000112		Major	Low	13/08/2024	19/11/2024	Closed
CC24172	ated artwork for the Wonderlab Women's Multivitamin and Wonderlab Men's Multivitar	HWFP000091 & HWFP000105		Major	Low	21/08/2024	21/08/2024	Closed
CC24173	Remove upper limit of calcium and magnesium from HWBG000076	HWBG000076		Major	Low	26/08/2024		Document not updated yet
			Sep-24					
CC24180	Hanyoo encapsulation machine into room 088TCR2	CAL949	s22	Major	Low	12/09/2024	17/09/2024	Closed
CC24181	Correct the unit of amount of label claim	HWBG000117		Major	Low	16/09/2024	7/11/2024	Closed
CC24183	New machine will be introdced in room no 88TCR2	CAL951		Major	Low	17/09/2024	19/09/2024	Closed
CC24187	MSOP and PM number for new sifter machine			Major	Low	19/09/2024		Machine yet to come
CC24191	Remove assay from HWRM000206	HWRM000206		Major	Low	25/09/2024		Document not updated yet
			Oct-24					
CC24193	Need to Update the Analytical Testing Method	ATM0327	s22	Major	Low	3/10/2024		
CC24200	NPD for Good Health Black Currant Beauty Coated Tablet (P)	HWBG000118		Major	Low	15/10/2024		Only BG Spec Updated
CC24201	Update Shelflife period to 3 Years and also update the listing information including the label claim of Silymarin, coated tablet weight, thickness	HWBG000104		Major	Low	15/10/2024	6/02/2025	Closed
CC24208	Update BG specification	HWBG000058		Major	Low	22/10/2024	13/11/2024	Closed
			Nov-24					
CC24217	Update RM spec	HWRM000476	s22	Major	Low	19/11/2024	19/11/2024	Closed
CC24219	Create new Fpcode for HWBG000059	HWBG000059		Major	Low	20/11/2024	27/11/2024	Closed
CC24224	Sustitute required for new supplier and manufacutrer for HWRM000295 & HWRM000161	HWRM000295, HWRM000161		Major	Low	26/11/2024		HWRM000161 not updated yet
CC24225	Update HWBG000120 BG spec of EZZ Bone Growth Chews Tablet	HWBG000120		Major	Low	29/11/2024		BG Spec Updated
			Dec-24					
CC24228	Site master File need to update (Key personnel change and organagram)	SMF001	s22	Minor	Low	9/12/2024	9/12/2024	Closed
CC24229	Update Wonderlab mens multivitmain create a new vitamin Premix	HWBG000073		Major	Low	9/12/2024		NPD in progress
CC24231	A new fridge (EQC114) will be introduced into QC Lab by replacing the old one (EQC028).	SOP QC0073		Major	Low	12/12/2024	17/02/2025	Closed
CC24232	NPD for EZZ Liver Tablets BG			Major	Low	18/12/2024		NPD in progress

Change Control Number	Details of Proposed Change	Code Number	Raised by	Impact level	Risk Level	Date Raised	Close date	Comments
			Jan-25					
CC25004	NPD for EZZ Liver Tonic Coated Tablet	HWBG000122	s22	Major	Low	10/01/2025		BG Spec updated
CC25005	Inclusion of New Supplier and manufacturer	HWRM000196, HWRM000209		Major	Low	10/01/2025		
CC25007	Weight Checker will be removed from 8 lane machine	NA		Major	Low	30/01/2025		
			Feb-24					
CC25011	NPD for ABM Freeze Dried NutriBites Vista	HWBG000123, HWFP000158	s22	Major	Low	07/02/2025		BG Spec updated
CC25012	NPD for ABM Freeze Dried NutriBites Lactoferin			Major	Low	07/02/2025		BG Spec updated
CC25018	NPD for Purity Sleep Support Coated Tablet (P)	HWBG000125		Major	Low	21/02/2025		Document not updated yet
CC25021	Supllier and manufacturer will updated	HWRM0000073		Major	Low	26/02/2025		Document not updated yet
CC25022	Identification B will excluded from sampling result sheet as per QID24081 and QID25008	HWRM000444		Major	Low	26/02/2025		Document not updated yet
			Mar-24					
CC25023	NPD for EZZ Magnesium Plus Coated Tablet	HWBG000126	s22	Major	Low	03/03/2025		Document not updated yet
CC25024	JBX product will be coded as Girraween Batch no.	HWFP000095, HWFP000140, HWFP00146		Minor	Low	03/03/2025	17/03/2025	Closed
CC25025	RM specification need to update by updadte Pb and arsenic limit	HWRM000454		Major	Low	03/03/2025		Document not updated yet
CC25029	NPD for Dailypure Support Liver Liver care & detox Tablet (P)	HWBG000127		Major	Low	10/03/2025		BG spec updated
CC25030	Eimele Red Consumer Box date coding style update	HWFP000156		Major	Low	11/03/2025	21/03/2025	Closed
CC25033	NPD for Fibalance Perdays	HWBG000128		Major	Low	13/03/2025		BG spec updated
CC25035	Update FP spec, packing instruction and PWO	HWFP000156		Minor	Low	17/03/2025	24/03/2025	Closed
CC25036	analytical test procedure (ATM-0408) By including addition:	ATM-0408		Minor	Low	18/03/2025		
CC25037	Introduction of Digital Heated Water Bath (EQC054)			Minor	Low	18/03/2025		
CC25038	Update raw material sampling result sheet by fixing residual solvent method and updating heavy metal, arsenic limit to 1.5 ppm	HWRM000485		Major	Low	20/03/2025		Document Not updated yet
CC25039	Update raw material sampling result sheet	HWRM000285		Major	Low	20/03/2025		Document Not updated yet
CC25043	Need to update Rm sampling result sheet by excluding total Impuritties	HWRM000491		Major	Low	24/03/2025		Document Not updated yet

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SITE MASTER FILE

HUNTINGWOOD

Document No: SMF001

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60 HUNTINGWOOD DRIVE
HUNTINGWOOD
NEW SOUTH WALES 2148

VERSION 08
DECEMBER 2024

Pharmaceuticals Pty. Ltd.
SITE MASTER FILE
60 HUNTINGWOOD DRIVE

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PREPARED BY:	CHECKED BY:	AUTHORISED BY:
Name: s22 [redacted]	Name: s22 [redacted]	Name: s22 [redacted]
Signature:	Signature:	Signature:
Position: QA Officer	Position: QA Validation Engineer	Position: QA Manager
Date:	Date:	Date:

INTRODUCTION

The Site Master file is related to the GMP Pharmaceuticals production facility at 60 Huntingwood Drive, Huntingwood, New South Wales 2148.

The site has been issued the Therapeutic Goods Administration (TGA) license (No.: MI-2019-LI-01002-1) for:

- The manufacturing of Powders Group.
- The manufacturing of Granules Group.
- The manufacturing of the solid dose form: Tablets
- The manufacturing of the Dosage Form: Capsule, hard.
- The storage of all dosage form.
- Physical Testing for all dosage form.
- Chemical Testing for all dosage form.
- Microbiological Testing for all dosage form.

The site has been issued Food manufacture Licence (No.: 25372) by New South Wales Department of Primary Industry and Biosecurity (NSW Food Authority).

The site has been registered by Commonwealth Department of Agriculture for Registration as Reg. Est. 1405. The site has been granted as an Export (Dairy) for dried milk and dried milk products, goat milk powder products producing, loading and storing Establishment.

The site has been issued Organic Certification (No.: 2638P) by National Association for Sustainable Agriculture (NASAA).

The site has been registered as a food facility, Registration Number: 18302201118, by FDA for the manufacture of supplement food.

An application for exporting dairy products has been submitted to the GACC.
Also, Huntingwood site is applying to the Therapeutic Goods Administration (TGA) for soft-gel packaging.

GMP Pharmaceuticals Pty. Ltd.
SITE MASTER FILE
60 HUNTINGWOOD DRIVE

1. GENERAL INFORMATION

1.1. The Company

Company Name

GMP Pharmaceuticals Pty. Limited

Company Name (Former)

Nature's Nutrition. The company was initially established in 1994 under the name Nature's Nutrition.

The name was changed to GMP Pharmaceuticals in 1999 to reflect a change in the company practices. Previously it was mainly a Sponsor of complimentary medicines with no manufacturing under its control but in 1999 the decision was made to become a manufacturer as well as a packer of therapeutic products and the name GMP Pharmaceuticals was selected.

1.2. Location of the Huntingwood Site

60 Huntingwood Drive, Huntingwood, New South Wales 2148.

1.3. Site Annexes

15 Long Street, Smithfield, New South Wales 2164 (storage only)

1.4. Other Company Locations but Independent of the Huntingwood Site

- 7 to 9 Amax Avenue, Girraween, New South Wales 2145.
- 14 Amax Avenue, Girraween, New South Wales 2145.
- 36 Amax Avenue, Girraween, New South Wales 2145.

1.5. Activities (Current) at the Huntingwood Site

Head Office and Administration.
Research and Development.

Food Processing (NSW Primary Industry).
Manufacturing of
Tablet, Powders (TGA licensing).
Capsule, Hard-shell
Tablet, Film coated
Granules
Packaging and labelling, all solid dosage form
Chemical and Physical Testing.
Microbiological Testing.

Storage (all dosage forms, TGA licensing)
Manufacturing, Loading and Storage for dried milk products (Dairy for Export) Department of Agriculture Registered Establishment No. 1405.

1.6. Activities (Proposed and future) at the Huntingwood Site

Processing of Dairy Product, dry powder (Department of Agriculture License).

Manufacturing of
Capsule, Enteric
Capsule, Modified release
Tablet, Effervescent
Tablet, Enteric coated
Tablet, Modified release
Packaging of Soft-gel dosage form.
(Therapeutic Goods Administration License).

1.7. Activities at other Independent GMP Pharmaceuticals Sites

Therapeutic (TGA Licensed):
Packaging and labelling, all solid, semi-solid and liquid dosage forms.
Manufacture of soft gel capsules.
Manufacture of hard-shell capsules.
Manufacture of tablets, uncoated and coated.
Manufacture of powders.
Manufacture of liquids.
Manufacture of lotions, semi-solids and creams.
Release for Further Processing.
Release for Supply.
Physical testing.

Therapeutic (APVMA, Australian Pesticide, Veterinary Medicine Authority Licensed):
Same as Therapeutic (TGA).
Dairy (domestic and export):
Mixing of dry dairy powders, including dairy by definition.
Re-packaging dry dairy (bovine) powders including dairy by definition.
Manufacture of dairy tablets.
Manufacture of dairy hard-shell capsules.
Food:
Products similar to therapeutic but not for therapeutic supply.
Manufacture of nutritional items.
Manufacture of health foods.
Manufacture of nutritional supplements.
Packaging and labelling of food products.
Cosmetics:
Manufacture of liquids, lotions, semi-solids and creams.
Packaging and labelling of cosmetics.
Organic:
Manufacture of Organic Certified products.
Packaging and labelling of organic products.
Miscellaneous:
Importation and distribution of health foods, nutritional supplements as well as cosmetics.
Importation and distribution of raw materials and packaging materials.
Design, production and importation of labels and other printed materials.

1.8. Licenses and Registrations at 60 Huntingwood Drive

Department of Agriculture Reg. Establishment (Reg. Est 1405) Manufacturing, Loading and Storage of dry Dairy Powders.

Product Manufacture Therapeutic Goods Administration (TGA No.: MI-2019-LI-01002-1) for Tablet, orally disintegrating.
Product Manufacture Therapeutic Goods Administration (TGA No.: MI-2019-LI-01002-1) for Tablet, Chewable
Product Manufacture Therapeutic Goods Administration (TGA No.: MI-2019-LI-01002-1) for Tablet, uncoated
Product Manufacture Therapeutic Goods Administration (TGA No.: MI-2019-LI-01002-1) for Powder
Chemical and physical testing Therapeutic Goods Administration (TGA No.: MI-2019-LI-01002-1) for all dosage forms.
Microbiological testing Therapeutic Goods Administration (TGA No.: MI-2019-LI-01002-1) for all dosage forms.
NSW Department of Primary Industry and Bio-Security (Food) # **25372.**
National Association for Sustainable Agriculture (NASAA) Registration 2638P
Halal Certificate for Supreme Islamic Council Of Halal Meat In Australia (SICHMA) #00712409GMP1/3K
Halal Certificate for Supreme Islamic Council Of Halal Meat In Australia (SICHMA) #00712409GMP2/3K
Halal Certificate for Supreme Islamic Council Of Halal Meat In Australia (SICHMA) #00712409GMP3/3K

Pharmaceuticals Pty. Ltd.
SITE MASTER FILE
60 HUNTINGWOOD DRIVE

1.9. Licenses and Registrations at other GMP Pharmaceuticals sites:

Therapeutic Goods Administration (TGA) 7 to 9 Amax: MI-21042005-LI-000516-1
Therapeutic Goods Administration (TGA) 14 Amax: MI-2016-LI-12063-1

Department of Agriculture (Export Dairy) 7 to 9 Amax: Reg. Est.: 1202
Department of Agriculture (Export Dairy) 14 Amax: Reg. Est.: 2255

NSW Dept. Of Primary Industry and Bio-security: 7 to 9 Amax License 25372
NSW Dept. Of Primary Industry and Bio-security: 14 Amax License 25372

Australian Pesticide, Veterinarian Medicines Authority License 2205

National Association for Sustainable Agriculture (NASAA) Registration 2638P

1.10. Company Contacts

Company Name: GMP Pharmaceuticals Pty. Limited.
Site Address: 60 Huntingwood Drive, Huntingwood, New South Wales 2148.
Postal Address: Refer to site address.
Telephone Number: (currently) s22 [redacted]
Fax Number: (currently) (s22 [redacted]
E-mail: info@gmp.com.au
E-mail s22 [redacted] @gmp.com.au
E-mail s22 [redacted] @gmp.com.au
E-mail s22 [redacted] @gmp.com.au
24 Hour Contact Number: s22 [redacted]
A.B.N.: 80 063 353 006
A.C.N.: 063 353 006

1.11. The Site (60 Huntingwood Drive):

The Huntingwood site is located in an industrial area 7km West of the Girraween facilities. It is located on a major secondary road (Huntingwood Drive) in the suburb of Huntingwood.

Immediately across the road is Arnott's Biscuits and a park. To the left, when facing the building, is the Eastern Creek Tavern, then two transport companies, a food manufacturer, an importer, New South Wales Police Highway Patrol base. At the rear is a building materials supplier, a cosmetics supplier. To the right is a distribution warehouse.

The building structure is about 20 to 25 years old. It consists of a concrete and steel skeleton on which walls and other materials have been affixed to create rooms and working areas. The total floor are is approximately 17,200 sq.metres. Of this, the office areas are 3,375 sq.m., the plant room is 116 sq.m., and the production and stores areas are 13,369 sq.m. The inner areas of the building are being fully refurbished to accommodate the production activities as well as the analytical and microbiological testing areas. Also to be included will be a purpose built R and D area. This to enable trials to be conducted in an isolated area away from the production areas. The floors are essentially reinforced concrete with walls and ceiling constructed of sandwich or insulation panel.

The size of the block of land is 27,340sq.m. Apart from the basic buildings, it includes landscaped areas as well as car parks.

1.12. Employees:

The site is new to GMP Pharmaceuticals and the introduction and commissioning of new activities has commenced and is on-going. As production expands there will be an increase in production as well as support staff.

The following numbers are expected to increase significantly when full production is achieved.

The numbers are related only to production and direct support staff such as maintenance, quality departments, stores as well as technical. The numbers do not include general office, accounts, customer services, IT, sales and marketing staff.

Production:	30
Production Planning:	2
Quality Assurance & IPQC:	7
Quality Control (Analytical):	10
Microbiological Analyst:	3
Maintenance:	2
Regulatory:	1
Storage and distribution:	4
Engineering, Facility:	5
Total:	64

It is expected that from time to time there will be a need for casual staff in the production areas. These staff will be employed on an “as required” basis and will be limited to performing simple packaging work.

The frequency of use, as well as the numbers of casual staff will be minimised where possible.

1.13. External Technical Services:

These are to be determined.

1.14. Quality Management:

The Quality Policy of the Company is:

“GMP Pharmaceuticals Pty. Limited is a provider of contract manufacturing and packaging services for pharmaceutical and nutritional products and is dedicated to providing products and services to a standard, based on “The Code of Good Manufacturing Practice”, the current Pharmaceutical Inspection Co-operation Scheme (PIC/s) issued in 2024 is the basis on which therapeutic systems are based. It is our hope to meet or ideally exceed the quality expectations of our many local and international customers.

It is one of our objectives to be recognised as a leader and innovator in our industry. One aspect of achieving this objective is the establishment of a Quality System. We believe that our Quality Systems are suitable to provide the necessary confidence that the quality needs of our customers, in addition to the requirements of “The Code of Good Manufacturing Practice” are satisfied in the products and services that we provide. Additionally, that the necessary controls are consistently and adequately applied to meet them. We believe that among other considerations to achieve this objective and to ensure we provide the highest possible standard of service; we should be supportive and committed to working with our customers to identify what their expectations as well as their stated and implied needs are. We also acknowledge that we should develop a partnership with our customers to maintain and continuously improve the quality of the products and services that we provide, thereby improving the quality of our operations and enhancing the benefits we provide.

We understand that to achieve these objectives we should, amongst other considerations promote the skills acquisition of our employees and to promote the concepts and benefits of quality throughout the organisation thereby encouraging the further commitment of our personnel to producing products of the highest standard.

As a respected corporate citizen, we affirmatively accept our obligation to achieve and maintain a high standard of environmental responsibility commensurate with our position within our industry as well as the community.

GMP Pharmaceuticals is committed to be an international best practice competitive food and pharmaceutical manufacturer meeting or exceeding its customer's needs.

A systematic approach is used to integrate the principles of continuous improvement throughout all levels and functions of the organisation, involving all management and employees and working in partnership with our customers and suppliers to achieve the stated food and pharmaceutical safety and quality objectives.

The food safety and quality system (including HACCP, export and importing country requirements) are adhered to at all times ensuring a reliable and hygienic manufacturing procedure to maintain product integrity, built on high quality ingredients to achieve the best possible product to fulfil our customers' expectations and requirements."

The food safety and quality system is continually reviewed, and upgraded as appropriate, to achieve continual improvement of product quality in response to changing customer demands, or system/process improvements. Adequate resources are provided for the implementation, control and review of the food safety and quality system.

The company is committed to producing safe, suitable products in compliance with all legislative requirements and ensuring that no procedure within the Food Safety and Quality System takes precedence over any requirement of the ANZ Food Standards Code, the Export Control Act and the subordinate legislation and regulations.

The Food Safety and Quality Manual is maintained as an integral element of the company culture, recognizing and encouraging full participation of all employees in the development and maintenance of the food safety and quality program.

The Quality Assurance (QA) function of the Huntingwood site has the responsibility of ensuring that all the relevant aspects of the Code of Good Manufacturing Practice are adhered to. QA also has the responsibility of ensuring that specifications are complied with and that a safe, efficacious and consistent product that is free from contamination is delivered to our customers.

With regard to the organisational structure, the QA Manager/Delegate Huntingwood reports directly to the General Manager or equivalent. Currently, there are five QA personnel reporting to the QA Manager/Delegate and they are in charge of implementing the various aspects of the Quality System as well as their day to day applications. The Quality Management System will be based on the Code of Good Manufacturing Practice for therapeutic products as well as the requirements of the New South Wales Department of Primary Industries and Bio-security requirements. Additionally, the requirements of the Export (Milk and Milk Products) Control Orders 2021 will be incorporated.

Specifications have been established for raw materials that are based on the appropriate compendia or another suitable references. Sampling and test procedures have been established for all incoming raw and packaging materials and have ongoing documentation for data collection and trend analysis.

An internal review programme has been initiated where Standard Operating Procedures (SOP) are evaluated for compliance and suitability at the time of their date of review.

In regards to internal and other audit reports, these are documented with a written corrective action request prepared and brought to the attention of the appropriate manager and a written reply is required. A compliance record is maintained with any undertakings and times for remedial action in the reply. As the business is still relatively small, any non-compliance with the SOP as well deviations from approved housekeeping practices should be observed during inspections and audits as well as tours of the various areas.

Standards such as ISO 9000 to 9004 do not have formal recognition at the present time. However, informal credence is given to these certifications when determining what quality control procedures are required for goods received from suppliers/manufacturers.

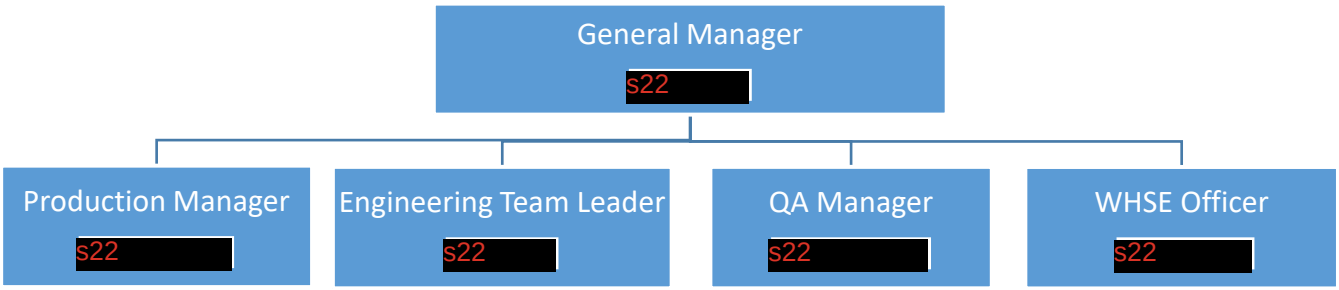
Suppliers of critical raw and packaging materials shall be assessed on what, if any, certification they have, then on their general reputation with regard to quality. Deliveries of these goods will be subjected to a level of quality control adequate to provide the level of confidence necessary for their use.

The “Release for Supply” (Therapeutic) or equivalent procedures for products manufactured on this site requires that all manufacturing and packaging documentation be evaluated including the results of the reconciliations. Only if the requirements of the evaluation process are complied with, will the product be “Released for Supply” or its equivalent.

For products contract manufactured by another manufacturer, who must have a current TGA license (Therapeutic) or HACCP (Food), or Organic Certification (Organic) or Department of Agriculture registration (specific to the requirements of our registration), the requirements are an acceptable certificate of analysis from the primary manufacturer. Also, all packaging records and reconciliations are evaluated. Only if the requirements of the evaluation process are complied with will the product be release as appropriate.

2. PERSONNEL

2.1. Organisational Chart.



2.2. Key Personnel and Their Qualifications.

Managing Director: s22

Master of Science (China). A number of years involved with pharmaceutical sales and marketing. He had completed a number of vocational courses related to the pharmaceutical industry. Responsible for overall business and its activities, ensuring that adequate resources, are available to the managers in line with the business needs.

Chief Operating Officer: s22

Graduate Bachelor in Bio-Engineering (Major in Biological Pharmacy), and Master of Biotechnology in University of New South Wales. s22 has in excess of ten years working experience in the pharmaceutical industry. He is responsible for the implementation of overall operations of the business. s22 has a broad understanding of the pharmaceutical industry. He started at GMP Pharmaceuticals in Marketing and later was given the role of Production Manager. From there he was promoted to Operations Manager and later was again promoted to the position of General Manager. Because of the various positions that he has held within the company, s22 has a good understanding of the nature and requirements of the pharmaceutical industry.

General Manager(Huntingwood & Girraween): s22

s22, the General Manager of GMP Pharmaceuticals, holds a Bachelor of Information Technology from Macquarie University and a Master of Information Networking Systems from Western Sydney University. s2 has been with GMP Pharmaceuticals for over nine years, starting as a supervisor in the TGA-registered warehouse. In 2020, s2 was promoted to Girraween Site Manager, and by the end of 2024, he was announced as the General Manager of GMP Pharmaceuticals.

Quality & Compliance Manager (Huntingwood Chemical & Microbiological Laboratories): s22

Bachelor of Science (Applied Chemistry) from University of Technology, Sydney, Australia. Over thirty years' experience in the pharmaceutical industry. s22 started his career with Reckitt & Colmen as raw material leader. He then worked for Bristol-Myers as the Laboratory Supervisor. s22 joined GMP over twenty years, he has been adding values to the team and GMP with his expertise in compliance, quality assurance systems, continuous improvement as well as the countless innovations in enhancing our product's quality and compliance. He has been promoted as Quality & Compliance Manager and overlook Huntingwood chemical and microbiological laboratories.

Production Manager (Huntingwood): s22

Bachelor of Science (Chemistry), India and Master of Business Administration, Australia. s22 has over 6 years of experience within the pharmaceutical as Production Supervisor and Production Manager. He initially started his career with Soft Gel Manufacturing, GMP Pharmaceuticals, after he promoted as Production Manager, GMP Pharmaceuticals. With the expansion of GMP Pharmaceuticals he has worked with several different departments (Soft Gel manufacturing, Dry Manufacturing, Freeze-Dry Manufacturing, Sachets Manufacturing, Liquid Manufacturing, Powder Bottle Manufacturing) as Production Manager.

QA Manager (Huntingwood & Girraween): s22
Bachelor of Engineering (Chemical Engineering) from East China University of Science and Technology, China, and Master of Engineering (Oil and Gas Engineering) from University of Western Australia. s22 has over 8 years of experience in the pharmaceutical industry, starting as a Softgel Machine Operator with Ferngrove Pharmaceuticals. After around half a year hardworking, he was transferred to QA department as a QA officer. He then became a QA Associate at GMP before being promoted to the position of QA Assistant Manager for Huntingwood site. At the end of 2024, he was promoted to QA Manager to look after both Huntingwood and Girraween site.

Engineering Team Leader (Huntingwood):

s22 is an accomplished Engineering Team Leader with a strong background in mechanical engineering and business strategy. He holds a Master of Commerce in Business Strategy from the University of New South Wales and a Bachelor of Engineering in Mechanical Engineering from the University of Queensland. With over a decade of experience, s22 has successfully managed multimillion-dollar projects, including overseeing $15M manufacturing and packaging lines, leading a team of engineers, and ensuring timely and budget-conscious project delivery. In his role as Project Engineer, he spearheaded a $5M freeze-dried production project, achieving a 98% yield within three months, upgraded facility equipment to reduce operational costs by 30%, and implemented preventive maintenance programs to minimize downtime. As a Design and Sales Consultant, Kian designed heating products, maintained strong client relationships, and secured new business opportunities, while his earlier role as a Production Engineer saw him enhancing fibre optics production efficiency by 50% through innovative problem-solving. His expertise spans project management, technical validation, energy optimization, and client relationship management, making him an asset in engineering leadership.

Quality Control Manager: s22

s22 holds a Master of Science in Chemical Analysis and Laboratory Management and has accumulated twelve years of experience in the pharmaceuticals and environmental testing industries. He commenced his professional journey as a Quality Control Analyst at Pharmaxis, an esteemed Australian pharmaceutical research company with TGA and FDA-approved laboratory and manufacturing facilities. During his tenure at Pharmaxis, s22 was responsible for conducting stability and development testing of raw materials, in-process materials, and finished products. Additionally, he received training in Occupational Health and Safety (OHS) and participated in internal auditing. Subsequently, s22 joined Eurofins, a globally renowned commercial laboratory, as the Organic Team Leader. In this role, he gained extensive experience in analytical method development, instrument maintenance, troubleshooting, and enhancement of the laboratory quality management system.

WHSE Officer: s22

s22 arrived in Australia in 2007 as an international student to pursue a master's degree in professional accounting from Ballarat University. Prior to this, he completed a bachelor's degree in accounting from S.P. University in Gujarat, India. Following the completion of his studies, s22 operated his own business until 2018. During this period, he developed a strong interest in Work Health and Safety (WHS) and subsequently obtained a Certificate IV and a Diploma in WHS from TAFE NSW.
s22 then transitioned into the role of WHS Officer for various companies before joining GMP in November 2023. In his current position, his focus is on reducing lost time injuries and fostering a robust safety culture at GMP.

2.3. Basic and In-house Training.

Currently, the training needs of the personnel may be determined by a number of means and consists of a multi-level approach.

1- Pre-deployment
After initial employment by the company but before employees begin performing duties within the production areas, they will be provided with simple training to ensure that they have a basic understanding of what is required of them. Operators will be given an outline of what is acceptable conduct within the working area. For example, all staff that perform duties directly related to the production or manufacture of therapeutic goods are required to have a basic understanding of hygiene as well as document control and data entry. While those involved with the production of dairy & food products will be additional training in sanitation.

2- Induction
Induction will be in the form of a structured program where new employees will be trained in the basic requirements related the Therapeutic Good Manufacturing Practice or Dairy and Food Manufacture as well as the necessary information related to hygiene and sanitation as related to food products.

3- GMP Training Program
This is a structured multi-module in-house training program. One of the main functions of the training program is to enable the various staff members to understand and appreciate the aims of the Code of Good Manufacturing Practice. This enables them to understand the procedures that they will be expected to follow. Included within this program will be training relevant to dairy products as well as foods. Staff are assigned duties relative to their understanding of the Code as well as their level of training.

4- SOP Training;
This will include training in Standard Operating Procedures, the various documents that are used, the specific use of equipment, general aspects of Good Manufacturing Practice and their duties.

5- Evaluation
Currently, the efficacy of the training is assessed by conducting quizzes designed for each SOP as an addendum to SOP and/or evaluating trainee's job performance. The assessment of the training is currently determined at the time of training and consists of evaluations that the trainees are required to undertake. If a trainee is determined not to be trained to an acceptable standard, they may be provided with further training to raise their standard or they may be assigned duties suitable to their demonstrated level of ability

A Training Record will be stored automatically in Master-control and manually in training register where register is maintained showing the various units of training that the personnel have received.

2.4. Health Requirements of Personnel.

Prospective production staff are required to undergo a medical examination and provide documentary evidence that they are medically fit and that their health is suitable for work within the particular part of the pharmaceutical or dairy and food industry with which this business is concerned. All staff will be required to notify their respective manager if their health deviates from this requirement.

Generally, the various departmental managers will be responsible for the health of the employees in their respective areas with the QA Manager having the additional responsibility of monitoring staff within the production area in conjunction with the Production Manager. Staff will not be permitted to work in the production area if they have any infections, lesions, wounds or injuries that have not been adequately treated and dressed. These requirements will be included in the in-house training programme. There are no critical areas that require a more detailed procedure at the present time.

2.5. Personal Hygiene and Sanitation.

There are adequate washing, changing and rest areas provided for all personnel. There are a number of areas throughout the premises that provide changing area facilities, personal lockers, showers, hands free hand washing area, hot air hand dryers, male and female toilets. Additionally, there are male and female toilets available in the office areas and which also provide, hand washing facilities and hot air hand dryers. All areas are readily accessible to all staff.

The protective clothing supplied to staff consists of a coat or gown which may have the company logo on it. Visitors will be provided with a similar coat. All persons entering the TGA areas will be required to wear approved gowns, hair coverings, shoe covers, facemasks and bear covers as well as any other appropriate protective items.

Sterile disposable gloves are also provided for use when required.

Staff are required to put on clean new gowns and other items each time they enter or re-enter a production area. There are sufficient coats to ensure a supply of clean new gowns or coats are available at all times. Coats are collected regularly and laundered before re-use.

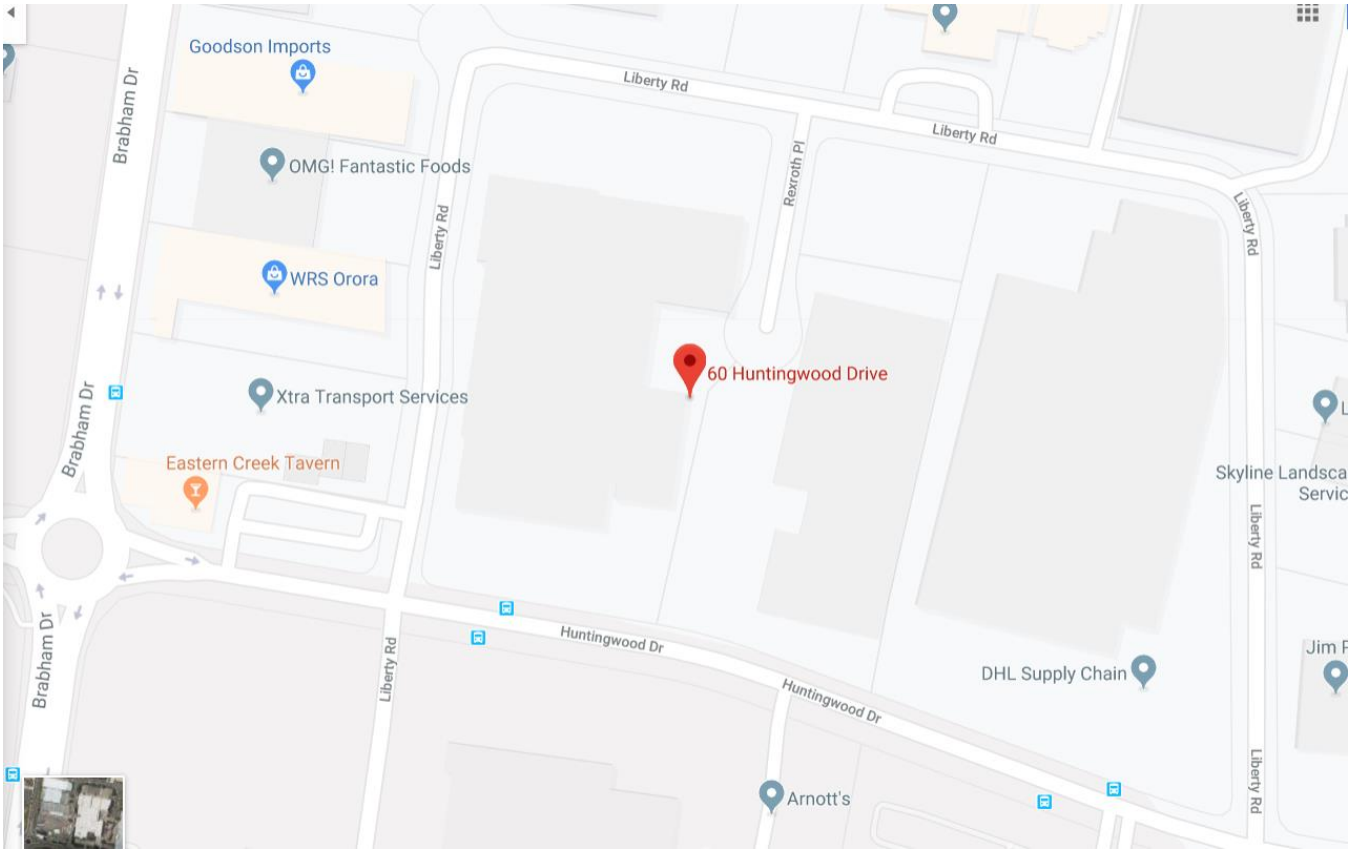
Staff are required to maintain a high level of hygiene and sanitation while in the production areas with sanitisation stations being readily available.

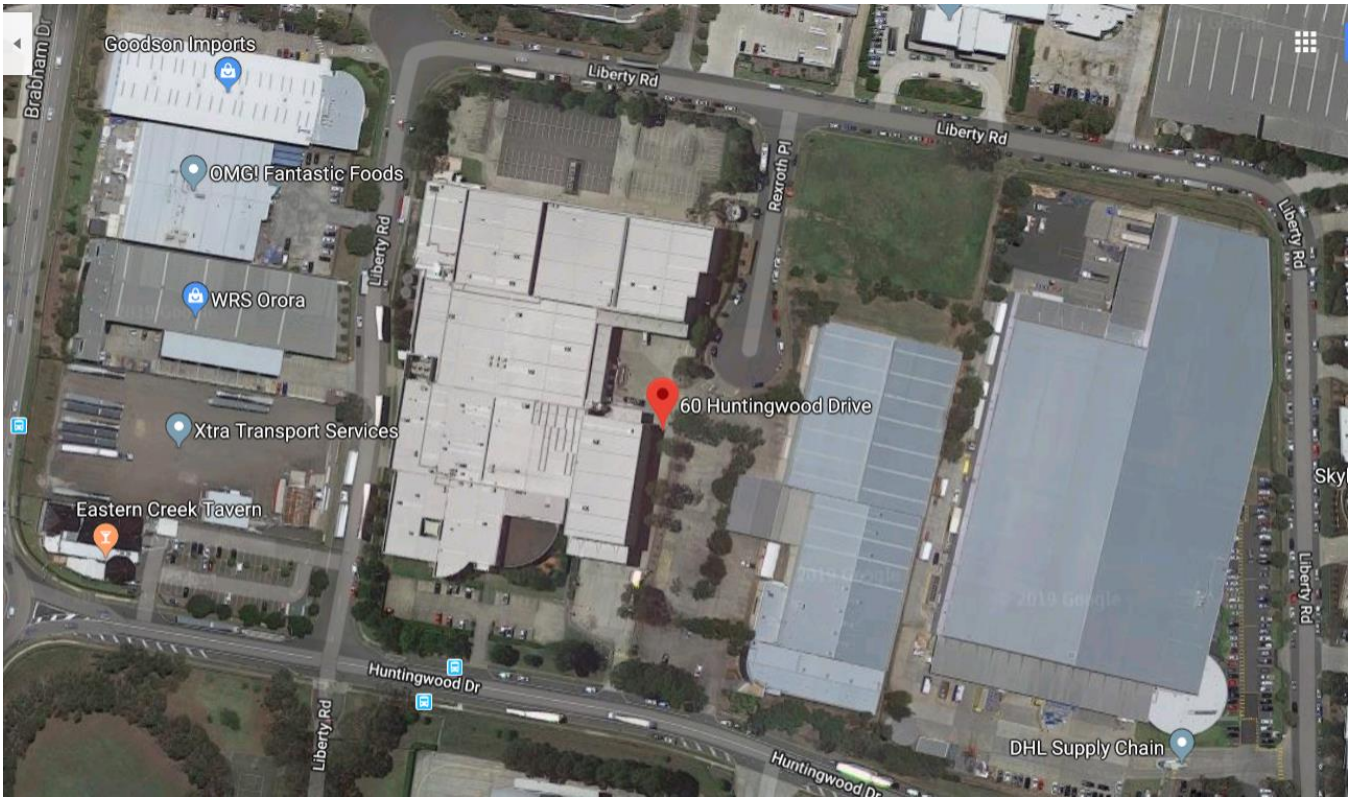
The company has a jewellery and other procedures to minimise the potential for foreign objects or other personal contaminants affecting products.

Areas are colour coded to minimise the potential for contaminants and allergens being carried from one area to another. All cleaning equipment where practical, comply with the requirements of the colour coding system.

3. PREMISES

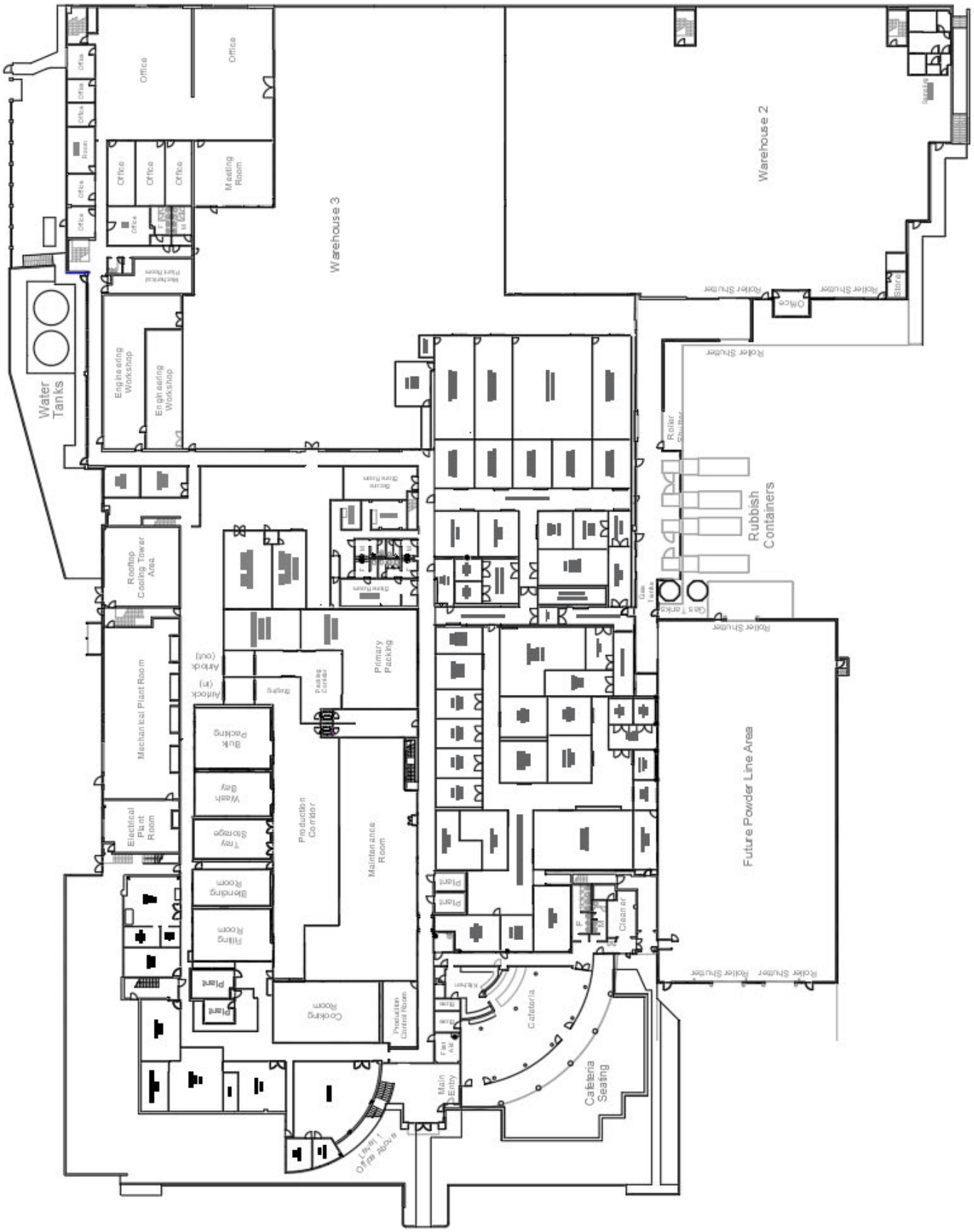
3.1. 60 Huntingwood Drive, Huntingwood, New South Wales 2148 (Aerial)





Pharmaceuticals Pty. Ltd.
SITE MASTER FILE
60 HUNTINGWOOD DRIVE

3.2. Buildings



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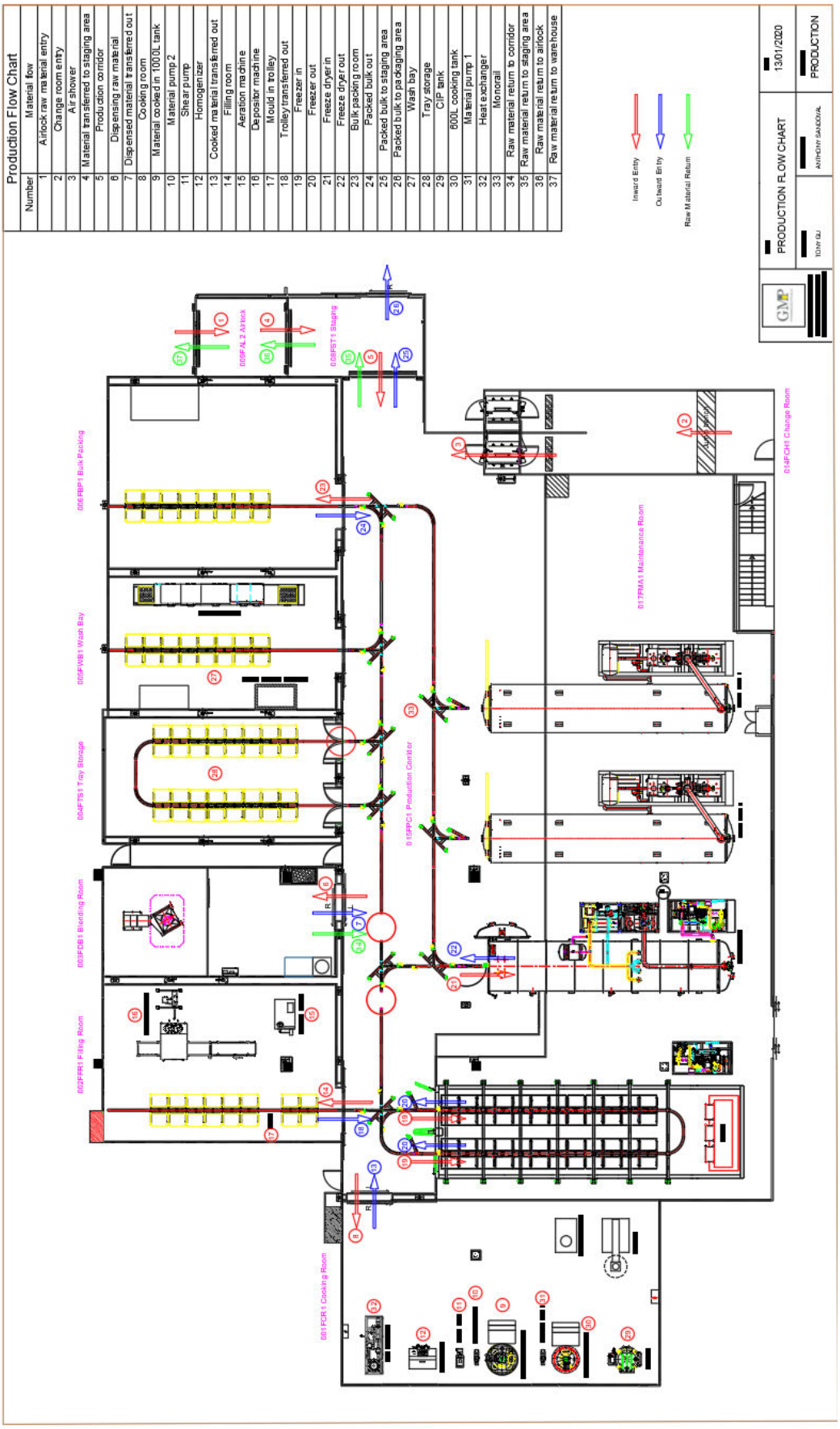
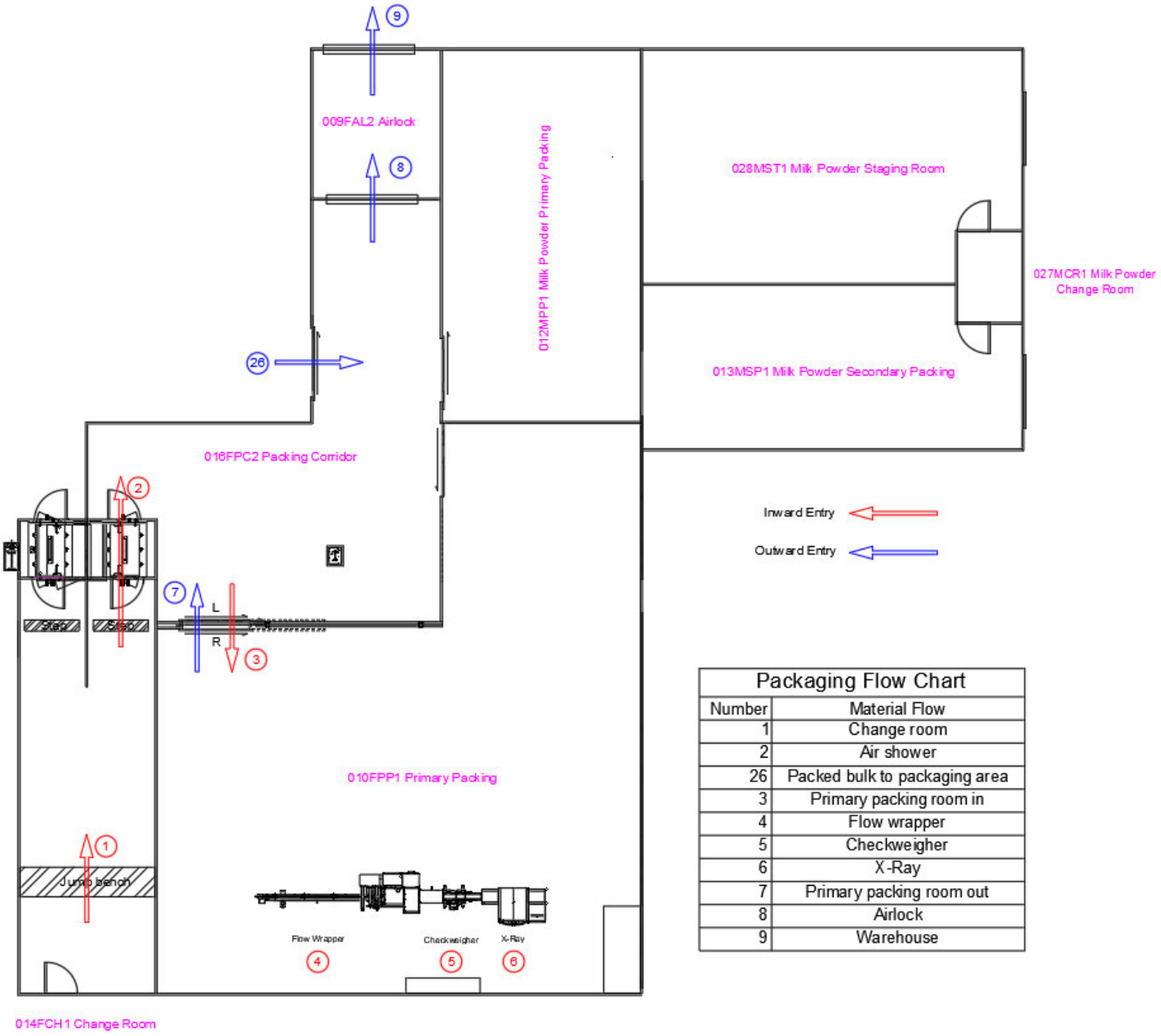
Freeze Dry Production Flow Chart



Pharmaceuticals Pty. Ltd.
SITE MASTER FILE
60 HUNTINGWOOD DRIVE

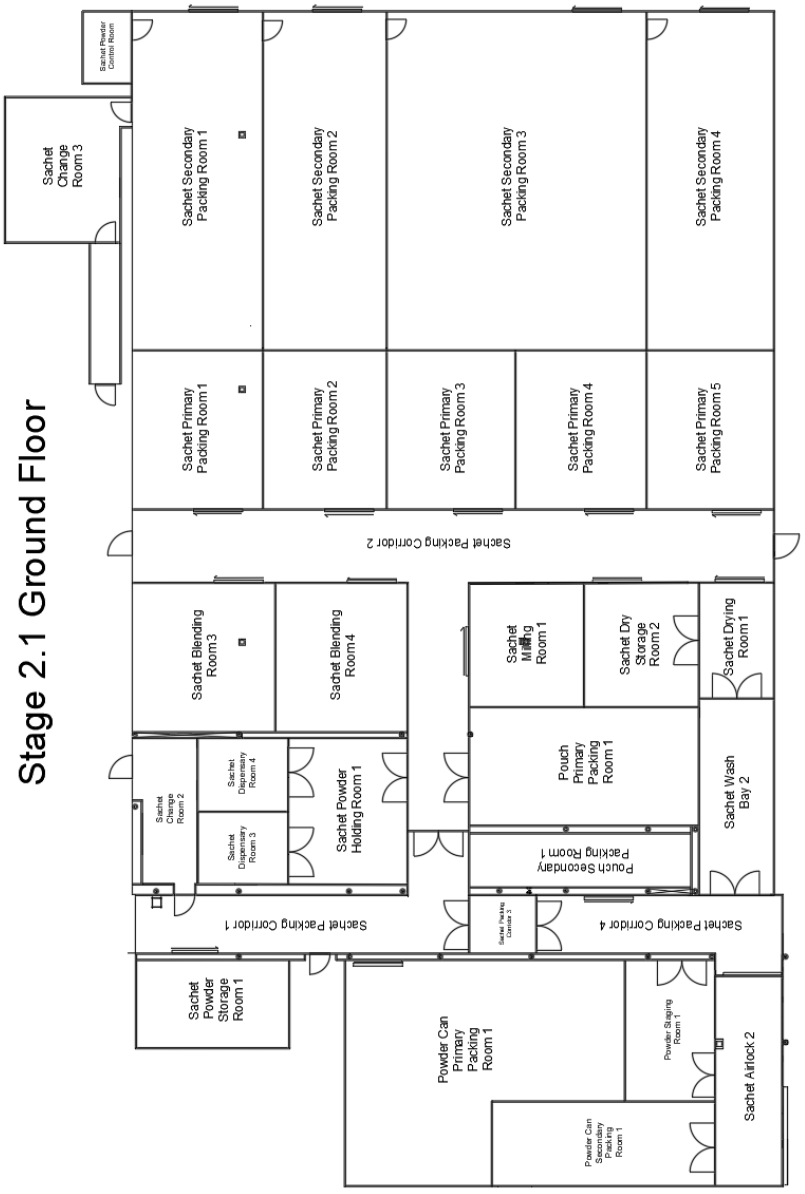
Freeze Dry Packaging Flow Chart



Packaging Flow Chart	
Number	Material Flow
1	Change room
2	Air shower
26	Packed bulk to packaging area
3	Primary packing room in
4	Flow wrapper
5	Checkweigher
6	X-Ray
7	Primary packing room out
8	Airlock
9	Warehouse

Pharmaceuticals Pty. Ltd.
SITE MASTER FILE
60 HUNTINGWOOD DRIVE

Powder and Sachet Line Flow Chart



GMP Pharmaceuticals Pty. Ltd.
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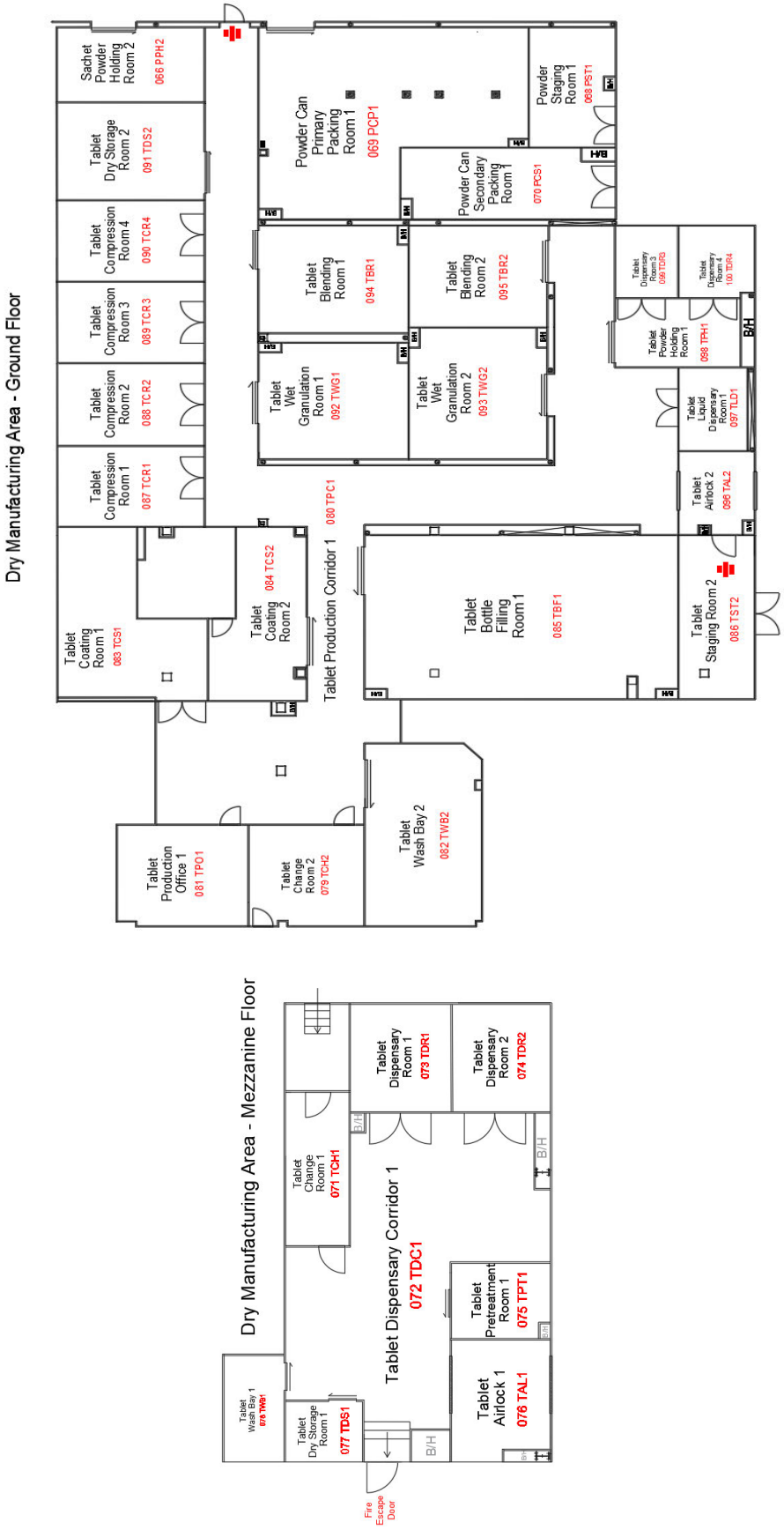
Tablet Line Flow Chart



Pharmaceuticals Pty. Ltd.
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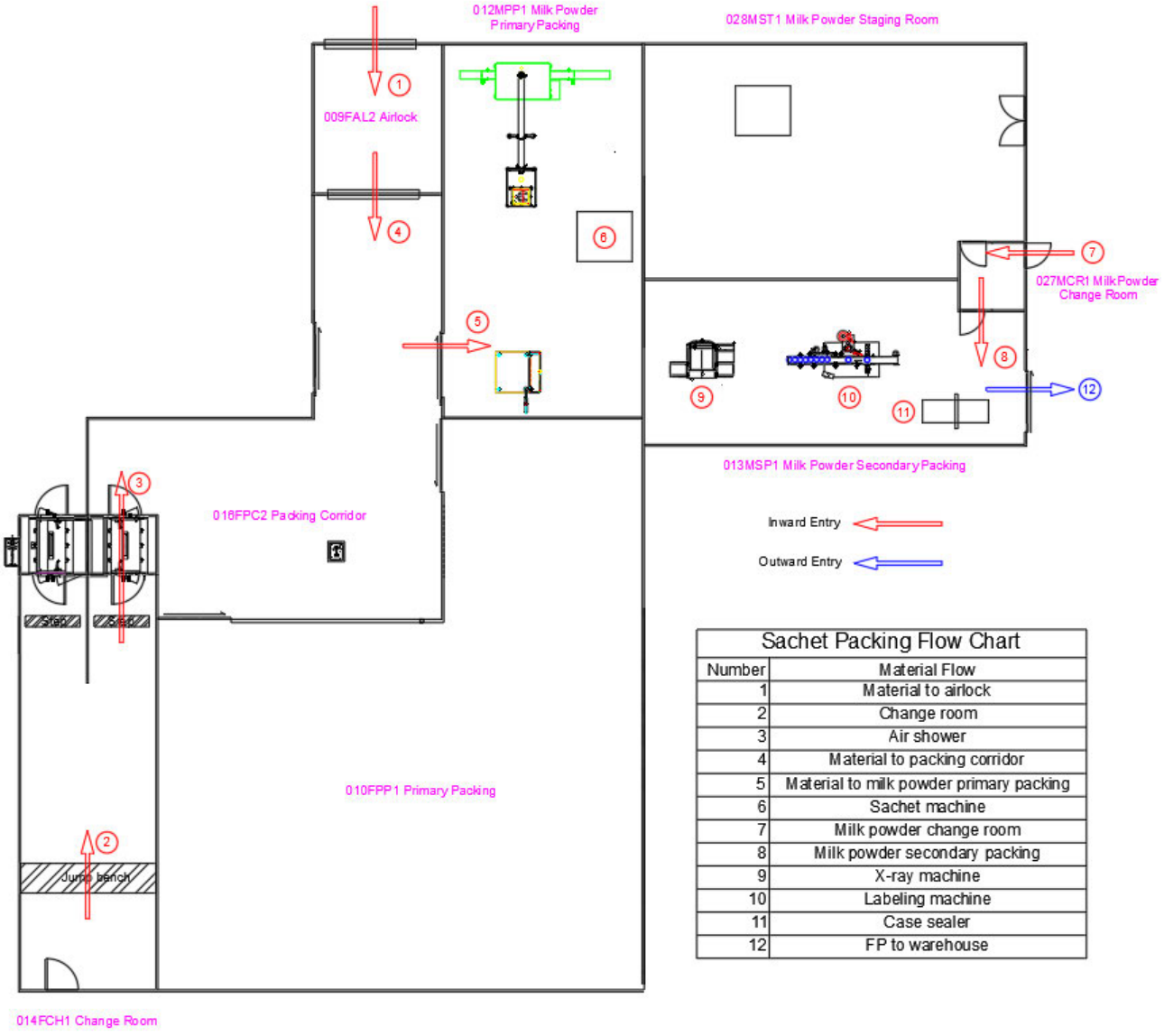
Powder Packing Flow Chart

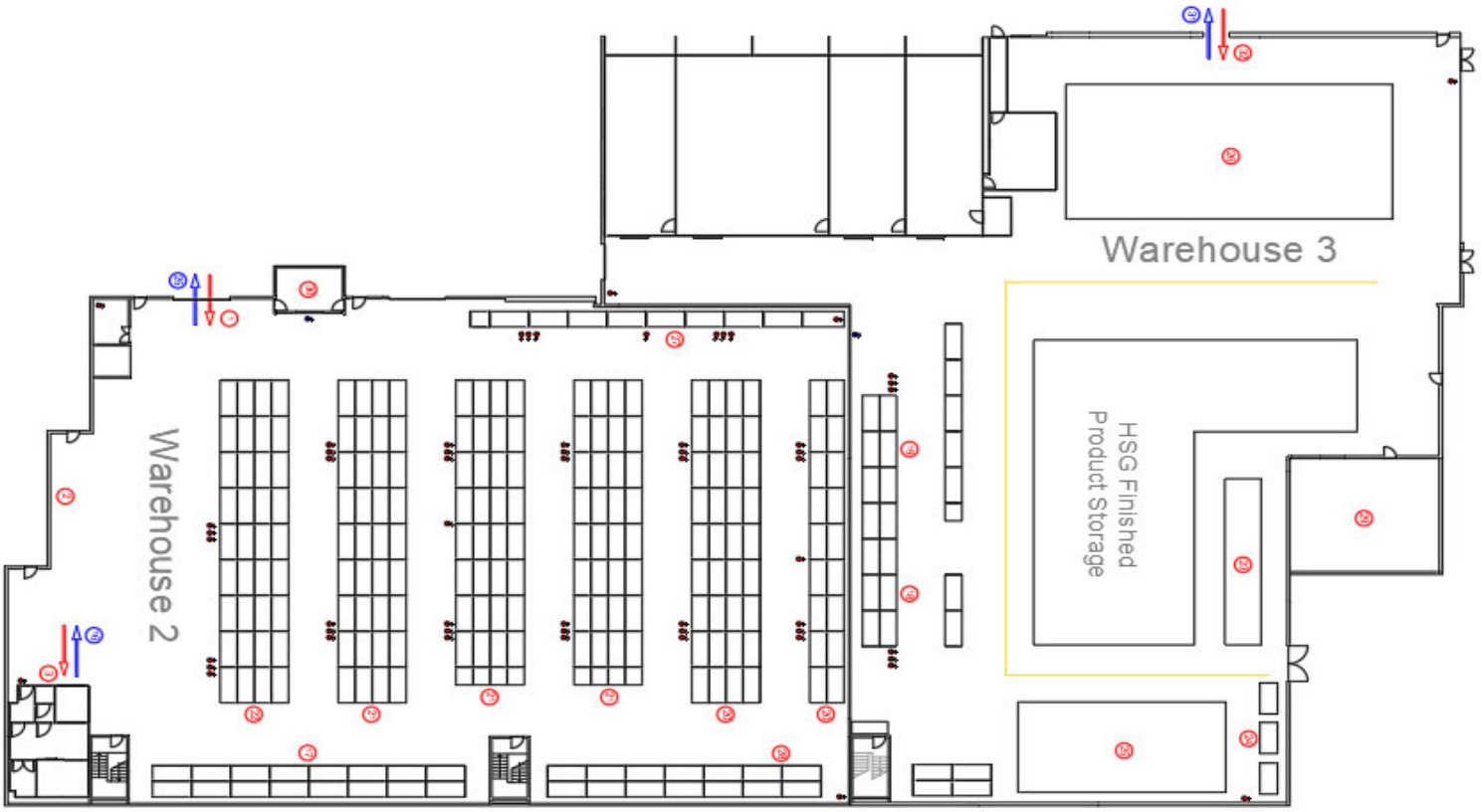


Sachet Packing Flow Chart	
Number	Material Flow
1	Material to airlock
2	Change room
3	Air shower
4	Material to packing corridor
5	Material to milk powder primary packing
6	Sachet machine
7	Milk powder change room
8	Milk powder secondary packing
9	X-ray machine
10	Labeling machine
11	Case sealer
12	FP to warehouse

Chemical and Micro Lab Area

Pharmaceuticals Pty. Ltd.
SITE MASTER FILE
60 HUNTINGWOOD DRIVE

Warehouse Flow Chart



Warehouse Flow Chart	
Material Flow	Number
Warehouse entry	1
Raw material staging	2
Raw material to airlock	3
Change room	4
Corridor	5
Raw material to corridor	6
Sampling room / raw material in	7
Sampling room / raw material out	8
Raw material move out	9
Packaging material to airlock	10
Packaging material to corridor	11
Sampling room (packing) in	12
Sampling room (packing) out	13
Packaging material to airlock	14
Packaging material move out	15
Raw material quarantine	16
Pharmaceutical raw material	17
Non-Pharmaceutical raw material	18
Packaging material quarantine	19
Packaging material approve	20
Customer supplied packing material	21
Container	22
Freezer	23
Consumables	24
Finished product quarantine	25
Finished product release	26
Reject and hold area	27
Label storage room	28
Warehouse office	29
To production	30
From production	31
Data logger	32
Temperature display	
Walk path	

3.3. Construction and Finishes.

The building was previously owned by Sony and was used to product, Compact Discs (CDs), DVDs as well as BluRay Discs.

The basic structure was initiated in about 1992 with additions being made over the following years.

The basic office section of the overall building consists of a reinforced concrete structure and floor with gyprock or plasterboard interior partitioning.

The warehouse areas of the overall buildings consist of a steel frame to which concrete panels are attached to produce an external wall.

The roof is a metal construction with an uppermost layer of pebbles to act ballast to secure the roof as well as provide thermal stability to the area below.

The production areas use “insulation” panel as partitioning. The panel consists of fire retardant “foam”, PIR (PolyIsoCyanurate) with either a painted colourbond type of cladding or a stainless steel cladding.

There are a few pre-existing panels that are constructed of EPS (Expanded Polystyrene).

The site has been fully renovated to meet the requirements of GMP Pharmaceuticals.

3.4. Heating, Ventilation, Air-conditioning (H.V.A.C.)

Heating, Ventilation, Air-conditioning (H.V.A.C.) system has been designed by Delta Air Conditioning for the production areas.

The system will consist of a central unit where air will be chilled (or heated) then passed through a HEPA (high-efficiency particulate air) filter to reduce particulates. The air will then be sent to the various production rooms.

Air will be returned (collected) from the production rooms and returned to the chiller/heater for re-use. The air will be again chilled or heated as required and passed through the HEPA filer into the air handling system.

There will be about 10 to 15% make up air. This is fresh air that is to replace air that will be lost during distribution to the production areas as well as air losses within the production areas.

There is a general requirement that rooms have a +10 Pa differential to the corridors to reduce contaminants entering the production rooms where exposed product is present.

Rooms are generally required to have a minimum of 10 air changes per minute. This rate will increase depending on the nature of the rooms use as well at the potential for exposed product to be present.

After installation the HVAC System, Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) has been evaluated as part of the equipment qualification requirement.

There are ongoing monitoring of the effectiveness and compliance of the HVAC system to ensure that it provides the optimum level of protection to products and processes.

3.5. Special (Hazardous) Area

At the current time, no toxic, hazardous or sensitising materials are used. There is however, a “dangerous goods” area which is located within the warehouse for materials that fall into the category of dangerous goods. Currently, the only material that is covered by this is ethanol and concentrated detergents.

3.6. RO Water System

Purified water is a critical service to the site. RO Water will be provided using a Vertex Hydrapore Reverse Osmosis Water System. The system is identified by model number: SLE64040 and serial number: 64040212.

After installation the RO Water System, Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) has been evaluated as part of the equipment qualification requirement.

The determined system will be capable of producing sufficient purified water to meet current needs. The chemical and microbiological specification for the water produced bases on the British Pharmacopoeia monograph for Purified Water in Bulk. On-going testing performs monthly until such time as confidence in the system permits a reduction in the frequency of the testing.

Sanitation performs on a regular weekly basis and recorded.

3.7. Preventative Maintenance and Equipment Servicing.

A preventative maintenance programme with supporting logs will be developed in conjunction with the suppliers of machinery and equipment.

There will be written procedures with service and maintenance logs for equipment and machinery. The operator's of the equipment will have reports made known to them as well as have access to the service logs or copies of important information.

3.8. Equipment.

GMP Pharmaceutical Huntingwood site has fully installed Freeze Dry Production Line. The relative major equipment includes following items: cooking vessels, aeration machine, filling machine, freezer, freeze drying units, Blender as well as a packaging line for the production of freeze-dried therapeutics and powders.

GMP Pharmaceutical Huntingwood site has fully installed a powder packaging line to pack commercial sized bulk milk powder and collagen powder in smaller consumer sized packs. This will be a food process.

GMP Pharmaceutical Huntingwood site has fully installed a tablet manufacturing line, which includes dry blender machine, tablet press machine, wet granulation machine, coating machine and encapsulation machine.

3.9. Maintenance.

The Managers of the various areas will be responsible for ensuring that maintenance is performed and documented as required. The nature of the service or repair will be determined by the nature of the situation.

Records in the form of logs are to be maintained for the various items of equipment.

3.10. Qualification, Validation and Calibration

All equipment must be suitable for the purposes for which it is employed. New equipment will undergo Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) evaluations as part of the commissioning process. Equipment already in service will undergo a similar but retrospective evaluation to ensure that it is providing the level of quality that is required.

Critical equipment such as scales or balances will be checked for performance on a monthly basis and calibrated or performance checked (certified) annually.

Other measuring equipment will be checked as specifically decided for the instrument and will be calibrated or certified as required. The time interval will be decided upon in conjunction with the certifying party.

3.11. Sanitation, Hygiene and Pest Control

There are written procedures for cleaning the various items of equipment, the cleaning agents and their concentrations that are to be used as well as the frequency. Cleaning agents such as detergents will be approved for use before being available to staff.

Sanitising agents will be selected partly based on their stability as well as efficacy. Currently, only small quantities of sanitising agents are stored to prevent efficacy problems due to aging. These will also be approved for use before being available to staff.

There is an ongoing environmental monitoring program that requires that the various areas and air handling systems be monitored for microbiological contamination.

Cleaning and sanitation procedures are in place for the water system, air supply system and the dust extraction system with maintenance logs for documenting these procedures.

There is an ongoing pest control program with the reports prepared by the contractor being evaluated by GMP staff to determine the effectiveness of the program.

4. DOCUMENTATION

4.1. Preparation Distribution and Review of Documents

Currently, documents are being prepared using a standardised format/Template with Microsoft Word®. The documents are required to be personally or electronically signed by the author, the person checking the document for errors and then the authorising person as required. The date of issue is then written on the document if necessary. If electronically created then effective date automatically generated from the Master-control system. Each page of the document is identified as a master document which generated outside of the EDMS. Inside EDMS usually the master document has a watermark as “Released”. No document is recognised which does not have the signatures of the author, checker, authoriser and date of issue/Effective Date. The issue/effective, revision, retrieval and archiving of documentation is managed by the QA Manager or delegate.

Batch documents are initially given to the production manager or delegate after they have been issued by the Planning Department. The batch is manufactured or packaged with production staff making any necessary data entries. When completed, the Area Supervisor reviews the batch document and if satisfied, signs off. When the Production Manager is satisfied that the documentation is in order, it is given to the QA Manager or delegate to determine the disposition of the batch. The batch documents are then archived.

The QA Manager or delegate is responsible for the preparation, revision and distribution of all documentation relevant to the manufacturing and/or packaging of product.

The Master Documents are stored within the QA office of the business and Electronically generated copies within the Master-control system.

Documents concerned with the manufacturing of products are prepared and issued according to the relevant SOP and have a standardised format. There are documents for product specifications, raw material specifications, packaging specifications, approved labels and pre-printed materials, standard process instructions, batch records including packaging and QA release procedures.

A computerised inventory control system called “Pronto” is used to print out the assembly quantities of materials for either bulk manufacture or packaging and these hard copy batch documents that are to be checked for accuracy before issue. The system will not replace the current system where quarantine labels are used to identify items and approved labels to indicate their status.

The Pronto inventory system is not used for any physical status changes to materials. Status of materials is a manual process using physical labels which are applied to goods.

Documentation is controlled by the relevant SOP, which requires that all master documents be identified as such and available only to authorised personnel, who may produce and mark uncontrolled copies as required. Each master document will incorporate a distribution list of authorised copies if requires. This list will be used when a document is reissued to retrieve all copies of the superseded version.

All documents will be maintained for a minimum of five years after they have expired or been superseded.

Currently, most of the Master copy of documents are Electronic copy only and Gradually, all types of documents will be generated by using the EDMS. There is no plans to use electronic or microfilmed recording.

At all times, the requirements of the Code of Good Manufacturing Practice are used as a guide when documents are required and when being prepared.

5. PRODUCTION

5.1. Production Operation

The site is capable of dispensing the materials required for and then packaging solid dosage forms, soft-gel dosage form as well as freeze dried products such as “mouth dissolvable tablets”.

TGA license has been issued for the following:

- Storage of All Dosage Forms
- Testing of All Dosage Forms
- Finish Product Manufacture of Powders Group
- Finish Product Manufacture of Granules Group
- Finish Product Manufacture of Tablets
- Finish Product Manufacture of Capsule, Hard

The license for the site to manufacture food items such as dairy (milk) products for local supply and export as well as blend and re-package dairy milk powders.

The general procedure for the manufacture of a bulk product of all kinds is as follows:

Raw Materials are received and placed into the “Quarantine” area. The raw material has quarantine labels affixed anf the delivery is documented (booked in). The raw material is sampled and a “Raw Material Result Sheet” is created for the delivery. The relevant details are entered on the Raw Material Result Sheet, which also indicates the testing required. If the raw material complies with the requirements it is then “Approved” for use by having an Approved label affixed and transferred to the main store. The packaging and labels are treated in a similiar manner to the raw materials. A batch card/record is issued, which indicates the assigned batch number, for a particular product at which time the availability of the neccesary raw materials is confirmed as well as the availability of the required equipment. The materials are then dispensed in accordance with the issued batch card/record. The processing of the batch is then initiated. The operator is required to enter the relevant information onto the batch card/record during the processing of the batch. At the completion of the drying/demolding stage of the batch a sample is submitted for evaluation by Quality Control. If the batch complies with the requirements It is “Approved” and an approved label is affixed to the batch at which time it is ready for filling and the labeling. The filling and the labeling stages are also controled by the batch card/record which requires the operator to enter details. When the product is packed a reconcilliation is performed on the batch. If the requirements are complied with, the product is released for further processing by the QA Manager or someone delegated to perform that function. During processing, the batch is identified by it unique identification or batch number.

If it is nessessary to transfer the batch to storage containers, these containers will have “In-process Identification” labels affixed and if appropriate “Approved” labels will also be affixed.

The general procedure for packaging is as follows:

If the product is of GMP Pharmaceuticals manufacture, it will be made available to the packaginng area after it has been approved and approriate status labeles affixed.

If the product has been received from another manufacturer it will be treated in the same manner as raw material and if acceptable it will be apparove for use and approriate status labels affixed. It will then be made available to the packaging area for us.

Packaging and printed matter are treated in a similar manner to raw materials.

After the various components are approved for use approved labels are affixed where required. The required batch instruction/record is issued, which indicates the assigned batch number. At this stage the required packaging materials as well as the capsules are taken to the packing room. The process capsules filling is the conducted in accordance with the batch instruction/record. The batch records are given to the Production Manager or someone delegated to perform that function for initial checking to determine if the documentary

requirements and the reconciliations are in compliance with the requirements. The packaging document is then reviewed by QA Manager or someone delegated for that purpose to ensure that all requirements and reconciliations are within specification and that any non-conformances and deviations are accounted for and that approriate reports are prepared. The goods are then released for further processing or supply depending on the discretion of the QA manager or delegate.

5.2. Handling of Starting (Raw), Packaging Materials and Finished Products

Each delivery of a starting or packing material is given a unique identifying number, in the case of this company it is called a GIN number (Goods Inward Number).

The materials are sampled or inspected in accordence with the SOP for sampling.

The status of the materials is identifed by labels such as Quarantine, Approved or Rejected.

Materials may only be issued if they have been approved for use.

Materials being used for manufacture are identified and released for use manually.

Where appropriate in-process checking is employed to assist in cntrolling the quality of the batch and when formally employed the batch documents will require that the operator record the results on the batch documents.

Line clearance checks are incorporated in the packaging/labeling instructions

Before product is permitted to leave the premises reconcilliations of the bulk product and packing and labeling materials are conducted. The product is released for sale or further processing only if the results of the reconcilliations comply with the requirements.

5.3. Reject Materials.

Non-conforming materials and products that have been rejected for use are clearly labeled with a “Reject” label which clearly identifies the material or product and its identification number. They are stored in a segregated area.

In the case of non-conforming raw materials they will either be returned to the supplier or disposed of as waste, whichever is appropriate. In the case of product it will be either reworked if possible or disposed of as waste again whichever is appropriate. Appropriate notations will be entered onto the log.

5.4. Process Validation

Process validation will be performed on seleceted manufacturing processes based on grouping.

6. QUALITY ASSURANCE and QUALITY CONTROL

6.1. The Quality Assurance and Quality Control System

Incoming raw materials are sampled and where required these samples are either chemically analysed internally or sent to an authorised external analyst for analysis for evaluation before approval. Internal and external laboratories will be suitably licensed or accredited. Certificates of analysis are examined against specifications. Testing results are compared against the specification before release. The source of materials is checked against an Approved Supplier List.

Incoming packing components are inspected, tested and compared to specifications before approval as well has having their source checked against an Approved Supplier List.

Incoming printed materials are inspected and compared against reference standards before approval.

Review of batch documentation, release of final documentation as well as the preparation, revision and distribution of documents is performed within the QA area.

7. CONTRACT MANUFACTURE and ASSURANCE

7.1. Contract Manufacture and Assurance

Contract Manufacture:

In the event that outside manufactures are used to provide product they are required to be licensed by the Therapeutic Goods Administration (TGA) or licensed by a third party that is approved by the Therapeutic Goods Administration (TGA). Additionally in each case a GMP Agreement will be established between the product provider (contract acceptor) and GMP Pharmaceuticals (contract giver).

Compliance will be monitored by the use of a formalised auditing process.

Contract Analytical Testing:

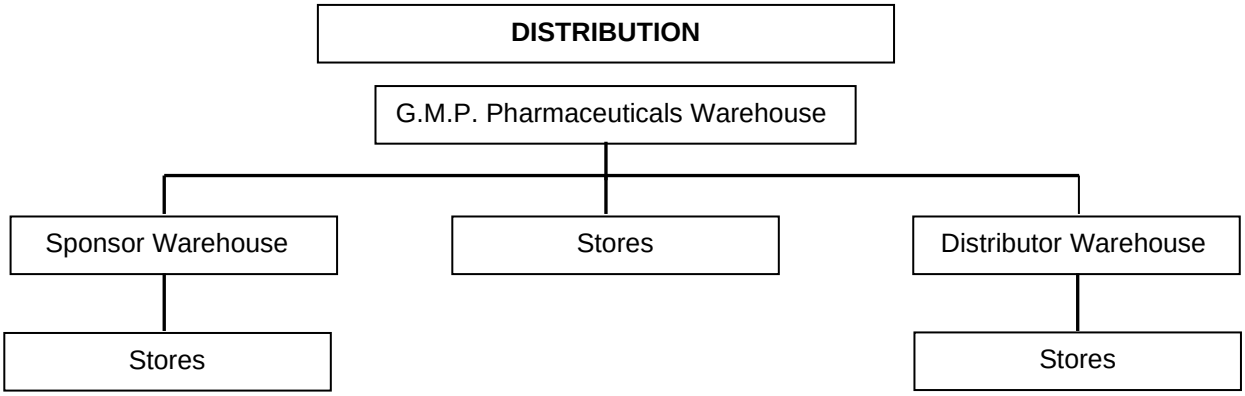
Providers of analytical support will be required, wherever possible, to be licensed by the Therapeutic Goods Administration (TGA) as well as being NATA Registered.

Additionally, in each case of a therapeutic product a GMP Agreement will be established between the product provider (contract acceptor) and GMP Pharmaceuticals (contract giver).

8. DISTRIBUTION, COMPLAINS AND PRODUCT RECALL

8.1. Distribution

The warehouse is a secure location, but is not environmentally controlled. There is refrigerated storage available. Materials are stored using pallet racking with their status being identified by the use of labels. Bin locations are also used to locate materials.



8.2. Complaints and Product Recall

The retained records permit full traceability of product manufactured and delivered to customers. The date of supply, the customer details and the quantity despatched as well as the batch numbers are recorded.

A written SOP is used to deal with complaints with the QA Manager or delegate being responsible for the procedure including, logging, classifying and investigating the complaint. Written reports are maintained for each complaint with the reports being reviewed initially by the QA Manager or delegate and then the General Manager. These reports will be maintained for a minimum of three years. There will be an annual report circulated to all managers that details the complaints received.

A written SOP is in place which deals with product recalls and which includes retrieval of distribution data, notification of customers, the receipt/ segregation/ inspection of returned product, investigation/ reporting of cause and reporting corrective action.

The QA Manager or delegate records and analyses product complaints and is responsible for notifying the Competent Authority (the TGA) of a potential recall situation as well as for co-ordinating an actual recall.

Although detailed batch records are not generally maintained by the various sponsors and distributors, it is believed that the information available would be sufficient to effectively enable a recall of a very significant quantity of product at batch level.

9. SELF-INSPECTION

9.1. Self-Inspection System

Self-Inspection is performed on a regular basis as per an internal auditing programme with the objective to ensure that all business operations are in compliance with SOP and regulatory requirements. Reports on the audits are written and brought to the attention of the appropriate manager and a written reply is required. A compliance record is maintained with any undertakings and times for remedial action in the reply.

The quality systems currently in place are effective for the products that are currently manufactured.

The internal auditing system and the requirement for the documentation of follow-up actions are covered by a SOP.

10. FUTURE DEVELOPMENTS

10.1. Future Developments

While it is not possible at any stage to state that a specific event, requirements, policies, practices, procedures or capabilities will be in place at some stage in the future it is possible to give an indication of what the company has as an intention.

10.2. Site Development

The Company has acquired the site with the intention of renovating it to be able to manufacture and pack tablet and repack dairy milk powders for export. It is intended to have testing facilities NATA registered.

10.3. Therapeutic (TGA).

An application has been made for Therapeutic Goods Administration (TGA) licensing for:
Packaging of all types of products.

10.4. Therapeutic (APVMA).

The company does not have an APVMA license for this site. The company has no plans to apply for an APVMA license but if they do it will only manufacture products that are consistent with the TGA license.

10.5. Food (NSW Department of Primary Industry and Biosecurity)

There are plans to prepare various other freeze dried dairy based products and pack them.

10.6. Department of Agriculture

It is expected that production of dairy products will be established in the near future based on Commonwealth Department of Agriculture export registration.

10.7. Other Products and Services

The company is considering what other products or types of products may be considered for manufacture, provided that they do not have any effect on the therapeutic or food products.

Pharmaceuticals Pty. Ltd.
SITE MASTER FILE
60 HUNTINGWOOD DRIVE

PUBLICATION AND REVISION HISTORY

Issue Date	Document Reference	Change No.	Details of Change	Previous Version	Current Version
August 2019	Site Master File No. 60 Huntingwood Drive	New	New	New	01
January 2020	Site Master File No. 60 Huntingwood Drive	CC20001	Update details for NSW food licence, organisation structure Updated document Number	01	02
February 2021	Site Master File No. 60 Huntingwood Drive	CC21007	Update details for TGA licence, Personnel Change, Production Status, Equipment and Facility Update and Future Plan.	02	03
November 2021	Site Master File No. 60 Huntingwood Drive	CC21060	Update drawings in the file and Licence	03	04
13th April 2022	Site Master File No. 60 Huntingwood Drive	CC21065	Updated dosage forms. Update drawings and organization chart in the file	04	05
18th Oct 2022	Site Master File No. 60 Huntingwood Drive	CC22068	Update dosage forms. Update Organization Chart	05	06
5th July 2024	Site Master File No. 60 Huntingwood Drive	CC24136	Update organization Chart at point 2.1 and updating point 2.2 by as per updated organizational chart.	06	07
09th December 2024	Site Master File No. 60 Huntingwood Drive	CC24228	• Soft-gel Packaging information included in Introduction • Packaging and labelling, all solid dosage form and Soft-gel information added at point 1.6. • Halal Certificate Information added at point 1.8 • Company Contact Information updated at point 1.10. • Update organizational chart as at point 2.1 and updating point 2.2 as per updated organizational chart. • At point 4 Electronic document management system information added.	07	08

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

s22
Quality Manager
GMP Pharmaceuticals Pty Limited
60 Huntingwood Drive
Huntingwood
NSW 2148

Our Reference: PH23/20896

Dear s22,

Subject: GMP Surveillance Inspection of GMP Pharmaceuticals Pty Limited

Please find attached the inspection report for the surveillance inspection that took place at GMP Pharmaceuticals Pty Limited's Huntingwood facility on 3 – 4 April 2025.

Your response(s) to the deficiencies reported in the post inspection letter have been evaluated and have been accepted. Effective implementation will be reviewed at the next GMP inspection.

You should note that assessments made during Surveillance Inspections are based on a random and limited examination and verification of the manufacturer's documents. This inspection report does not therefore claim to be a complete evaluation of all manufacturing operations performed at your site, and does not release you from the obligation to rectify deficiencies that have not been identified or stated herein.

Should you have any questions regarding the inspection, please do not hesitate to contact me.

Yours sincerely

Signed and authorised by

s22
Senior GMP Inspector
Manufacturing Quality Branch

Date: 30 May 2025
Tel: s22
E-mail: s22@health.gov.au

Surveillance Inspection Report

Manufacturer:	GMP Pharmaceuticals Pty Limited
Inspected site/s:	60 Huntingwood Drive, Huntingwood NSW 2148
Manufacturer information:	GMP Pharmaceuticals Pty Ltd (GMPP) is a manufacturer of listed therapeutic goods. GMPP holds 3 TGA licences to manufacture listed therapeutic goods. All licenced sites are located in western Sydney, in the suburbs of Girraween and Huntingwood. The facilities have been commissioned for the manufacture of both food and listed therapeutic goods. The Huntingwood site is in a light industrial area approximately 7 kilometres west of the Girraween complex and has held a TGA licence since 2020. The Huntingwood site continues to expand its portfolio of medicinal products, primarily with additional solid unit dosage form products. The manufacture food products was excluded from the scope of this insepction.
Activities carried out by manufacturer:	☑ Manufacture of finished medicinal product ☐ Manufacture of intermediate or bulk ☐ Packaging ☐ Laboratory testing ☐ Release for supply ☐ Manufacture of Active Pharmaceutical Ingredient ☐ Other:
Type of inspection:	☑ Re-inspection ☑ Surveillance inspection ☐ Remote inspection ☐ Hybrid inspection Applicable sections of the *Therapeutic Goods Act 1989*: ☑ section 40(4)(b) (re-inspection of licensed site) ☐ section 25(1)(g) (overseas in relation to registration) ☐ sections 26(1)(g), 26A(3) (overseas in relation to listing)
Scope of Inspection	Finished product manufacture of listed medicine in powder, granule, tablet and hard shell capsule dosage forms. Packaging, labelling and release for supply of listed medicine in soft gel capsule dosage form. Storage and testing of listed medicine in all dosage forms.
Inspection date/s:	3 – 4 April 2025
Inspector:	s22 [redacted]

Manufacturing Standard used:	PIC/S Guide to Good Manufacturing Practice for Medicinal Products, Part I (PE 009-16)
References:	Manufacturing Licence number: MI-2019-LI-01002-1 Inspection tracking number: MI-2023-LI-03211-1 File reference number/s: PH22/23917 (inspection file), E19-540033 (licence file)

Personnel met during the inspection

s22 QA Manager
s22 Quality & Compliance Manager

Inspected areas, findings and observations

Refer to Site Master File, SMF001 version 8, effective December 2025, for information of site activities.

Major changes since the previous inspection:

- Multiple new products introduced to site
- Changes to key personnel at Huntington; replaced by suitably experienced staff from GMP Pharmaceuticals' Girraween complex
- Upgrade or replacement to some ancillary production and laboratory equipment

Future Planned Changes: None discussed

Quality Management	
Subject area inspected	**Compliance outcome / comments**
Review of actions taken since previous inspection	Deficiencies 1 & 2 recorded at this inspection were similar to deficiencies recorded at the previous routine re-inspections of May 2021.
Product Quality Reviews	Refer to deficiency 1. A similar deficiency was recorded at the previous routine re-inspection conducted in May 2021.
Change Management	Refer to deficiency 4
Complaints management	No deficiencies identified
Deviation, non-conformance and CAPA management	No deficiencies identified
Internal Audits	No deficiencies identified
Batch Record Review and Batch Release	No deficiencies identified
Training	Refer to deficiency 2. A similar deficiency was recorded concerning on-the-job training at previous routine re-inspections, including that conducted in May 2021.

Materials Management	
Subject area inspected	**Compliance outcome / comments**
Warehousing	Refer to deficiency 5
Starting Materials	No deficiencies identified
Production System	
Subject area inspected	**Compliance outcome / comments**
Production - Formulation Areas	Refer to deficiency 6
Production - Manufacture/Filling	No deficiencies identified
Production – Labelling/ Packaging	No deficiencies identified
Validation/Qualification	
Subject area inspected	**Compliance outcome / comments**
Process Validation	Refer to deficiency 4a
Cleaning Validation	Refer to deficiency 3
Computer System Validation	No deficiencies identified
Facilities and Equipment	
Subject area inspected	**Compliance outcome / comments**
HVAC	Refer to deficiency 7
Water Systems	No deficiencies identified
Quality Control	
Subject area inspected	**Compliance outcome / comments**
Chemistry Laboratory	No deficiencies identified
Control of OOS results	No deficiencies identified

List of Deficiencies observed during the inspection

Critical deficiencies:

None observed

Major deficiencies:

1. The requirement of Clause 1.10 that regular periodic or rolling quality reviews of all authorised medicinal products, including export only products, should be conducted with the objective of verifying the consistency of the existing process, the appropriateness of current specifications for both starting materials and finished product, to highlight any trends and to identify product and process improvements; and these product quality reviews (PQRs) should normally be conducted and documented annually, were not fully met. For example, there were no formal processes in place to ensure PQRs were available for all authorised medicinal products manufactured at site, and to ensure PQRs were conducted annually (or every 2 years for low volume products). The inspector noted that the available PQRs may represent the full product range; however, GMP Pharmaceuticals approved process was to conduct individual, product based PQRs, rather than using a grouped product approach.

2. The requirements of Clause 2.11 that newly recruited personnel should receive training appropriate to the duties assigned to them, continuing training should also be given, and its practical effectiveness should be periodically assessed, were not fully met. For example, processes for recording the effectiveness of on-the-job training had been formalised into procedures; however, the planned checklists for recording on-the-job training activities were still being developed and no records of on-the-job training were available.

Other deficiencies:

3. The requirements of Annex 15 §10.9 that where campaign manufacture is carried out, the impact on the ease of cleaning at the end of the campaign should be considered and the maximum length of a campaign (in time and/or number of batches) should be the basis for cleaning validation exercises was not fully met. For example, cleaning validation protocols associated with the extension of campaign manufacturing activities, outlined in Quality Incident report, QID 24124, did not specify hard to clean locations on equipment, which could be impacted by the extended campaign length, to ensure these were reviewed for visual cleanliness and microbiological build-up.

4. The requirements of Annex 15 §11.4 concerning change control, that quality risk management should be used to evaluate planned changes to determine the potential impact on product quality, pharmaceutical quality systems, documentation, validation, regulatory status, calibration, maintenance and on any other system to avoid unintended consequences, and to plan for any necessary process validation, verification or requalification efforts, had not been fully implemented. For example, new product introduction processes did not consistently evaluate the need for process validation, nor formally evaluate whether the new product should be included in the site's on-going stability program. For example, regarding Change Control CC24163 for the transfer of Wonderland Capsules from GMP Pharmaceuticals Girraween site to the Huntingwood site,
    a. CC24163 did not identify process validation as a requirement, nor was there an evaluation recorded to ensure the new product was represented by the existing process validation product groups.
    b. CC24163 did not evaluate the need for an on-going stability study for the new product. It is acknowledged that on-going stability for this product was underway at the Girraween site; however, this was not documented in the change control and it was unclear whether manufacturing processes at the Huntingwood site would be comparable to those used at the Girraween site.

5. The requirements of clause 3.19 that storage areas should be designed or adapted to ensure good storage conditions, [. . .] they should be clean and dry and maintained within acceptable temperature limits, and where special storage conditions are required (e.g. temperature, humidity) these should be provided, checked and monitored, were not fully met. For example, the warehouse temperature in the locations used for storage of gelatine capsule shells were not specifically monitored. The warehouse temperatures were monitored at the 'worst case' locations and temperature excursions were only actioned when temperatures were above 30 °C. There was no evidence available to demonstrate the storage locations for gelatine capsule shells would remain at or below 25 °C, as required by the special storage conditions of the material. The temperature records indicated the 'worst case' locations were above 25 °C (and below 30 °C) on multiple occasions during January and February 2025.

6. The requirements of clause 5.19 that cross-contamination should be prevented by attention to design of the premises and equipment as described in Chapter 3 of the PIC/S Guide, and this should be supported by attention to process design and implementation of any relevant technical or organizational measures, including effective and reproducible cleaning processes to control risk of cross-contamination, were not fully met. For example, wash bays on both the mezzanine level and ground floors of the Tableting/Dry Powder Suite were noted to have black residue on some horizontal surfaces within the wet areas of the wash bay. The residue was present in/on sealant between wall panels and floor coving, and upon multiple horizontal ledges around the wash bay enclosures.

7. The requirements of clause 5.21 regarding technical measures required to control risks for cross-contamination were not fully met as evidenced by the following,
    a. Appropriate use of air-locks and pressure cascade to confine potential airborne contaminant within a specified area were not effectively implemented (clause 5.21 (x) Technical Measures). For example, the pressure gauge reading for the wash bay on the mezzanine level of the Tableting/Dry Powder Suite indicated the pressure differential of the wash bay was positive to the central staging area of the mezzanine. This was not compliant with the facility design.
    b. On-going monitoring and preventative maintenance of the HVAC did not minimise the risks of contamination caused by recirculation or re-entry of untreated or insufficiently treated air (clause 5.21 (xi) Technical Measures). For example, confirmation of HEPA filter integrity in AHUs across the facility were limited to visual checks; however, this was not adequate to determine whether the HEPA filters had been perforated. HEPA filter integrity was a critical component of the sites HVAC design as the on-going monitoring program of room pressure differentials had no upper pressure limits, and AHUs had no pressure monitoring across their filter banks.

Comments
None

Summary and conclusions

Assessment of manufacturer's responses
A response to the deficiencies reported to the manufacturer was received on 5 May 2025. The manufacturer's corrective actions have been evaluated and accepted, based on the agreement that all corrective actions will be carried out as described in the inspection close out correspondence.

Final evaluation and recommendations:
1. The manufacturer operates in accordance with the relevant GMP requirements.

2. TGA records have been updated to show a final compliance rating of your facility of A2: satisfactory compliance with the manufacturing standard established under the *Therapeutic Goods Act 1989*.

3. The next re inspection is expected to be performed within 30 months.

4. The duration of the next inspection is estimated at this time to be 4 days and will be conducted as a Full Inspection.

Signed and authorised by

s22
Senior Inspector
Manufacturing Quality Branch

Date: 30 May 2025
Mobile: s22
E-mail: s22 @health.gov.au

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Manufacturing Quality Branch

s22 [redacted]

Surveillance Inspection Plan – Medicines & APIs

Manufacturer name:	GMP Pharmaceuticals Pty Limited
Manufacturer address:	60 Huntingwood Drive Huntingwood NSW 2148
Inspection type:	Surveillance re-inspection
Inspection dates:	3 – 4 April 2025
Inspectors:	s22 [redacted]
Inspection standard:	PIC/S Guide to Good Manufacturing Practice for Medicinal Products (PE009-16)

Time	Inspector	Activity/Element
Day 1:		
09.30-10.00		**Opening meeting** ☑ Introductions ☑ TGA updates ☑ Inspection Standard ☑ Inspection plan ☑ Review Application ☑ Buildings in scope of Inspection ☑ Company overview - description of manufacturing and product range ☑ Attendance record ☑ Inspection Process ☑ Inspection scope ☑ Breaks and use of facilities ☐ Batch records
		Pharmaceutical Quality System
10.00-12.30		☐ Change control (3) (1) ☑ Complaints ☐ Supplier Evaluation (1) ☑ Product Quality Reviews (7 grouping + timeliness) ☑ Computerised systems (8) (6) ☑ Deviation & NCR (6), CAPA, OOS ☑ Recall activities ☐ Training (4)
12.30 – 13.15		**Lunch**
		Materials Control / Warehousing
13.15 – 14.00		☐ Inventory Management System ☐ Raw Materials/Bulk Materials ☐ Rejects Control ☐ Retention/Reference Samples ☐ Temperature monitoring - warehouse mapping (2c) ☐ Status Control-Identification/Traceability ☐ Finished Goods ☐ Returned goods ☐ Cleaning/Housekeeping **Starting Materials** ☐ Sampling area/Plans ☐ Control of pre-printed packaging
		Production System
14.00-16.00		**Dispensing Areas** ☐ Materials Flow **Production - Manufacture/Filling/labelling** ☑ Gowning/Access ☐ Contamination control – air/layout ☐ Mixing/Blending ☐ Batch record formats/entries ☐ Process flow ☐ Cleaning procedures/records ☐ Cleaning ☐ Water supply Room pressure monitoring systems (6) Coating machine failure alarms (7) — Not reviewed **Dosage form specific equipment** ☐ Granules ☐ Powder ☐ Tablets (FC + disintegrating) ☐ Capsules

Time	Inspector	Activity/Element
16.00-17.00	✓	**Batch Record Review and Batch Release** ❒ Line clearance ❒ Traceability of materials ❒ Reconciliation ❒ Completeness/accuracy ❒ Environmental monitoring ❒ IPQC results ❒ Batch Release Process ❒ Marketing Auth./Regulatory compliance
17.00		**End Day 1**
Day 2:		
		Facilities and Equipment
8.30-9.30	✓ ✓	❒ Calibration – dispensary scales (3) **HVAC** ❒ Area Classifications ❒ Pressures/Containment strategy ❒ Monitoring/Control/Testing/Trends ❒ Handling of alarms and trending ❒ Environmental Monitoring(6) (2) **Water Systems** ❒ Sanitisation ❒ Monitoring/Control/Testing/Trends Water (6 alerts & actions for OOS) (8 - weekly monitoring)
		Validation/Qualification
9.30-10.30	—	☑ VMP (2) ☑ Process validation for NPI s22 [redacted] notes p2a ☑ Computerised systems ☒ Cleaning Validation (5 cleaning of chutes etc)
		Quality Control
10.30-12.00		**Chemistry** ☑ Specifications and test methods ❒ Reference standards ☑ Equipment calibration/maintenance ❒ Test results (raw data) ❒ System suitability ☑ OOS/OOT Procedures ❒ Test method validation 2f & 2g chem & micro ☑ Stability ☑ Instruments/Equipment ❒ Data Management
12.30 – 14.00		**Lunch & preparation for closing meeting**
14.00-15.00		**Closing Meeting**
15.00		**Depart site**

The times indicated are for guidance only and can be modified to suit.

GMP Pharmaceuticals Pty Ltd
Huntingwood

Total hours

26/3	1.0
3/3	7.15
4/3	6.00
	14.15
	00

Wed 26/3 8.10 – 9.10
Thur 3/4 5.25 (6.05–6.35) 9.35 – 16.50 17.25
Fri 4/4 8.20 8.45 – 14.30 --- 19.00.

#25040

Personnel △ – via CC – use embedded DA.
Multiple personnel (key) left GMP.

- Replaced with experienced staff from Greenweek complex.
  ↳ pastacing in inspect
- Recalls ? - any ? PRAC implementation
  ↳ Update to procedures.

Intro needs updating
15 Long St ?? Storage ?? PS sent

Deviations / NCR

OOS + lab incidents

CAPA

complaints

Batch records (ARTG listings)

Tabs F.C, disintegrating Pwd

- Document review period

Attendance opening Meeting

s22 [redacted]

Process Validation

- PV not noted on CC (d)
- PV grouping not updated (d)

— PV groupings scientific & recorded

New products added to relevant group-ing

This product needs check of encapsulation step (blending as per tablet blend uniformity)

Change Control (2022-2025 list provided)

CC 25040 - Update SMF

Org Chart
Key personnel

Comment → Missing is a thorough review of SMF
Basic info on activities doesn't reflect current licence (TGA)

15 Long St → used to store non-pharma materials

CC25036 ICP method update to include additional elements

CC 24193 Analytical method update
Δ to flow rate to improve resolution
↳ Verify %RSD PA < 1.0
No need for valid (agreed within BP allowance)

CC 2K163 NPD Wonderland Capsules (transfer from GW)
RnD — check equip + trial B.
· Doc prepared required + verified
— PV grouping evaluate not in CC.

CC 24201 △ Shelf life to 3yrs. (increase from 2yrs)

Based on sponsors stability data.

Daily Pure Support Liver Core ▽ Delox Coated Tbs

Stability sples taken on 1st new batch

Core made @ Huntingwood
FC @ Girraween

} Girraween take stability sple.

↓

onto Girraween stability program

Girraween is RFS

Complaints

4-5 each year 2024+2025

CCC25001 Black dots in tabs 14/1/25

RM — Medium — possible micro

Rtn sample — full micro test (including mould)

Not on retains
(B) MR all OK

Possible root cause oxidation of Fe to cause black spots.

↳ No Si sachet in bottle returned

CCC24001 21/4/2024

Adevaya AV Neodin coated tabs

→ Red dots on surface

Also retains — only 1B manufactured

∴ Caused by formula → ingredient bleeding then coating (coil API)

Client informed — No repeat orders

Derivatives p6

Q1D25001 Coding

25020 05

24124 Planned.

Tab (still open)

24146

P2R — Individual on each product

No schedule in place

2022 — 2 P2Rs

2023

↓

2025 — 5 P2Rs conducted.

① No evidence that 7 P2Rs cover full product range.

② No schedule to ensure timely conduct

eg Swiss Ultiboost Stress

2023·6 – 2024·5.

All criteria reviewed + OK

Quality Incidents

QID 24124 Campaign length extended from 7 → 14 days

Deviation raised for first time

↳ Take swabs for CV as per ~~paste~~ protocol @ day 14 for micro + Pd, Cd, As, Hg on equipment

(d) ↳ No consideration of hard to clean areas in protocol CLVP 001 & CLVP 002

QID 24446 OOS during stability study

↳ from Scientest contract lab

Stability is client responsibility (see p 6a)

QID 25001. Coating soln too thick - caused spray guns to clog.

Caused by adding ingredients in wrong order.

CA for that (B) – extra tech

PA – updated coating soln making process

E22 Phytomin Ca + Vit D3 + Vit K2 F.C.

16/10/2023 Initial time pt

Oct/2024 Vit K2 ≡ Menaquinone 7

All other actives in range.

↳ Sponsor notified

OMP not manuf. since

↓ Degrading across the study

from 29.1 µg/tab → N.D.

Spec 27.75 – 49.5 µg/tab

↳ Deviation open as still monitoring

005/25H/015 LOD + Assay batch 05

Phase I L-Proteose Pwd

	LOD	Assay (titration)
Spec	≤ 0.4%	98.5 – 101.5 %
Result	0.98%	97.9 %

↓ Excess H_2O in R.M.

Deviation – No wt adjustment needed
Use in (B)

Site Tour

Warehouse

2× Spl Room - Air lock enclosed
△ room
2× spray rms
wash bay

Pronto + labels to control quarantine/ approved.

1° Packaging printed — locked room - Temp control
Reject goods cage available
Temp monitoring for <30°C
Records @ hot spot show occasional
(d) — 26-27°C.

All warehousing clean & tidy
Material stored appropriately

Dispensing — In product + some in sampling booths

(Mezzanine)

Pretreatment Rm — Small scale blending

2x Sieving Rm — direct to lower floor bin (2000L)

(a) Wash Bay — Potential mould on sealant btw S/S wall-floor + on horizontal ledge @ ankle ht in wash bay enclosure

Clean equip Storage

DN bagged + tagged

(d) diff ints washbay +ve or -ve to staging area??

Gowning — Bunny suit
Head cover
Face mask — Wash + Sanitise hands
Gloves
Overshoes

Magnahelic gauge indicated washbay was +ve pressure to central mezzanine staging area, ~~although this was disputed by staff~~

Not as per design — reported 2 days prior inspection.

- No deviation ~~as~~ raised as yet.

All rooms +ve pressure to central staging area

- No formal verification conducted / documented to ensure this has happened.

Freeze drying equipment

Currently no pharma orders.

Tableting / Dry Prod lines

Washbay Black build up (scum, dirt, mould?) on top lip of covers @ floor.

2 x Blender Bin Rms - From dispensary to receive sifted material

2 x Bin blending rms

Wet granulat 1 x FBD (2 x PLCs ↓ on cpv list)

3 x compression

1 x Encapsulat

3 x Store Rms

Small packaging rm Small tubes

IPC Hardness only

Construct

Epoxy floors
SS/Al walls + ceiling
Coving
Recessed / covered lights

F. Coater — Solns prepared in separate area.

See close-out notes 2022

(d) Alarms recorded in audit trail
↳ only review if alarm reported.

Bottle filling line

Office / IPC lab — Disintegrat
Friability
Unif of Wt

Film coat prep rm
PW outlet in rm.

* 14 RO test pts. ~~(A)~~ P15

Sachet packing — Separate area.
Same design with suite / dispensing on mezzanine
⇓ bins on GF

2 × 12 lane sachet packer

2 x 8 lane sachet fillers

Pouch packer (1 lane)

Wash Bay - Wall bottom sealed
& black silicon

→ ~~DTG~~ Can't see
dissolvant

VMP

Updated to include 2022 close out requirements

EOMS Implementation CC 24066

Risk level – low due to high detectability of failure

Document control update, Validate "Master Control" Software Training

Master Control Application Suite Version 2023.4

↳ Validation Report supplied by vendor

Rpt 2324 implemented correctly @ site

User access levels

User Groups – Department

↳ Sub roles.

↳ Read only + attendance – Site specific. Majority of accesses

↳ Edit access limited

✓ User deactivation / lock account

Computerised Systems

EDMS – under implementation – cloud based (Master Control)

(b) ~~No list or register available for product / QA~~ → is available

(d) No audit trail review on ~~QC~~ film coater

Validn – covered by procedure

User access levels defined → assigned } covered under val or qual.

Register is pretty good QC data capture
FBD coater

No EDMS as yet as not fully implemented

Rpt 2025 VFR-00025

Functn + User profiles executn

Site Customisation – User Groups developed

→ Users assigned access during set-up by Master Control cont. p 14a

↓ possible verified by Master Control but not deliberately checked by Compl staff

(c) ———

Base User Groups

Computer system control from p13

Verified?

Batch assignment to staff – staff employee# – user group.

Possibly verified by Data Control

Update or change. – access.

(IT form available) for access + Δ's

Saved in system – can be tracked via audit trail review

Training

SOP based. + quiz

(d) OJT still not ~~formulated~~ implemented — In process.

↳ developing checklists for OJT for required areas.

PW

HVAC - ρ logged B4 use.
+ 2× day when in use

~~Annual replacement of HEPA filters~~

~~- filter Δ~~ - currently visual checks on HEPA filters only conducted (see below ⊛)

- EM procedure
2 rounds
↳ Comprehensive on isolate generally <2/plate
↳ Recent OOS in tablet area under investigat

+ RO H_2O 15 pts
↓ Monthly
↓
v. low counts <1 cfu/ml

PW

⊛ checks monthly on pre filter (G4) + intermediate (F7)
also tint pre-filter + G4 filter in the air in production
~~this~~ visual check for dirty → Δ as required.

HEPA. ¼ly service conducted by contractor on AHUs
↳ doesn't include integrity or pressure tests.

Room pressures are all ≥ values
No upper limits set.

Micro on every 10th product batch

BMRs

Code HWFP0001(1)

Wonderlab Luvia Detox H03096

Hard capsule GO's H03097
H03121 ⇐ F.P.

RFS Checklist — No check of stability data
2:0 cleared.
No micro
↓
from Giravveen.

Comprehensive & well executed BPR
BMR

" line clearances - detailed checklist

Dispensing labels with bar codes
- checked vs. formulation

Excellent documentation

Bioisland Lysine Starter for Kids Oral Pwd

Pouch
↓
Pack to sachet & then to Giravveen to RFS.

H02944
H02919 + H02920

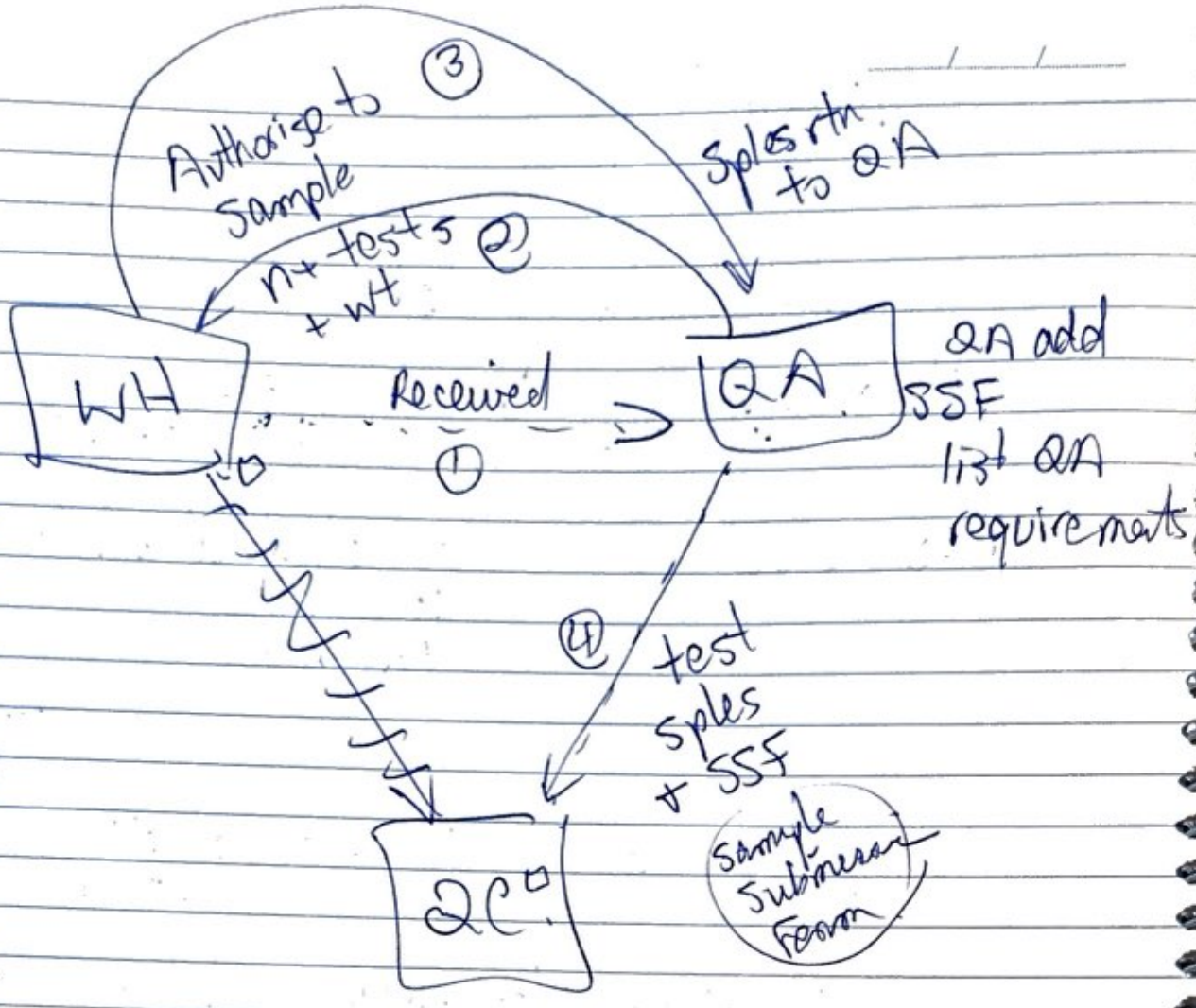
Similarly comprehensive

Chem Lab

Sample Receipt

See flow chart p17a.

- Polarimeter - saves data to unit
  copy to USB → print
  (d) - command ← 16GB USB used currently.
  No secondary back up implemented
- Water Activity (A_w) → direct read.
- Analytical balances
- Ref materials - Sigma + compendial
- pH, autotitrater x2 → direct read out
  + " printout of data
- Freezer ref storage
- Sample prep areas. - 60°C glassware dry
  105°C oven.
  DI H_2O


Authorise to sample
③
Spls rtn to QA
n+ tests + wt
②
WH
Received
①
QA
QA add SSF list QA requirements
④
test spls + SSF
Sample Submission Form
QC

Commercial std's used
1 - R.M tests
1 - residual solvents

Instrument Rm

5 x HPLC - OpenLab Server based.
2 x GC/FID - —— " ——
1 x ICP OES - HEP Expert (Agilent)
(Hard drive only)
1 x VV - Hard drive + Agilent software
1 x FTIR - —— " ——
1 x HPTLC - 10 herbals
Scan of plates

→ Manual backup to external hard drive 2 wkly.
High use equipment.

- FTIR — Ref spectra in logbook

→ Library (locked) → Sples
Can add spectra to library - special access privledges required. } requires 95% match

↳ traceable to ref material used to create.

- Regular PM (annually) by Agilent + service contract

didn't verify if ALL systems checked
↳ possibly limited to chrom.

for ~~all~~ systems ~~conducted~~ Audit trail review implemented for each cam

- Print out data + review.

Australian Government
Department of Health
Therapeutic Goods Administration

Manufacturing Quality Branch

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Close Out Record - Final

Manufacturer name:	GMP Pharmaceuticals Pty Limited
Manufacturer address:	60 Huntingwood Drive, Huntingwood, NSW 2148
Inspection type:	Re-Inspection & Licence Variation
Inspection dates:	10 – 13 May 2021
Inspectors:	s22 [redacted]
Inspection standard:	PIC/S Guide to Good Manufacturing Practice for Medicinal Products (PE009-14)

CAPA review from 2021 for inspection

Major deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
1. The requirements of Clause 5.27 that the selection, qualification, approval and maintenance of suppliers of starting materials, together with their purchase and acceptance, should be documented as part of the pharmaceutical quality system, the level of supervision should be proportionate to the risks posed by the individual materials, taking account of their source, manufacturing process, supply chain complexity and the final use to which the material is put in the medicinal product. The supporting evidence for each supplier/material approval should be maintained was not fully met as evidenced by: a. The Huntingwood site relied on supplier approval program conducted at their sister site (Girraween) but this was not covered by the GMP agreement between the sites (Also refer to Clause 7.1).	Please note : CAPA plan required as evidence for critical and major deficiencies that includes root cause analysis, corrective action/s to the root cause, preventative action/s to the root cause, corrections to observed examples, and due date for completion of actions. See headings below to be used for the response Response date: 16/07/2021 Identified Root Cause: Two sites (Girraween and Huntingwood) are sharing one procurement team, which can save the time for raw material sourcing. But the job of supplier qualification is not clearly arranged in Huntingwood site. Some of the suppliers and manufacturers were approved and qualified by Girraween site, but Huntingwood site did not evaluate. Also, the sampling plan should be full sampling for the raw materials from these unqualified suppliers until they are qualified in Huntingwood site.	16/07/2021	Review 1 It is acknowledged that updates have been conducted to address deficiencies in SOP QA0026 and QA0038. This should prevent future non-compliance but the current status of Jiaherb, Euromed and VASA Pharm is not clear. Please provide information on the approval status of these suppliers given the lack of qualification observed at inspection and if there is any impact on product manufactured to date.	Y – 1a-1d, 1g, 1h N – 1e, 1f, 1i

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Close Out Record - Final

Major deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
b. The periodic review of key suppliers in SOP QA0026 was not defined. c. The Approved Supplier List (ASL) was not up-to-date or adequately controlled in the QMS. In addition, the supplier & manufacturer's address was not stated in the ASL to fully identify the approved supply chain. d. For Jiaherb supplier; the questionnaire was reviewed by the Girraween site but there was no evidence that this had been accepted by the Huntingwood QMS. e. For Euromed; the supplier was currently being used for active ingredients (Passion Flower) without the completed questionnaire as required by SOP QA0038. f. For Magnesium Citrate, only the supplier (Redox) had answered the questionnaire. There was no assessment available for the manufacturer VASA Pharm. g. √n+1 was permitted for sampling containers of active materials from unqualified suppliers in SOP QA0038 (Also refer to Annex 8 §2). h. SOP QA0038 required full testing on the first three deliveries of new raw materials but did not specify for three	Corrective action/s to the Root Cause: GMP agreement between GW site and HW site is updated to cover the shared duty for evaluating and auditing supplier/manufacturer. SOP QA0026 is updated to include detail of periodic review and the procedure of evaluating questionnaire approved by GW site. New form QAF077 Supplier/Manufacturer Questionnaire Assessment and Approval Form is introduced. Added one column for manufacturer address into R23 Approved Supplier Register. SOP QA0038 is updated to amend the sampling plan for active raw material from unqualified suppliers. Amended full testing from first 3 delivery to first 3 different lots from the supplier. Preventative action/s to the Root Cause: Sample results sheets for Raw Materials will provide more information about the sampling quantity to avoid mistake. Corrections to observed examples: SOP QA0026 and QA0038 have been updated accordingly. The questionnaires of Jiaherb, Euromed and VASA Pharm have been verified using the newly issued form QAF077.			

Repeat issues
- WH temp monitoring
- OJT documentation
- PQR

No attendance sheet

s22 [redacted]

Major deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
different lots to ensure qualification testing covered lot-to-lot variability. i. Sampling of all containers (for ID) was not observed for the unqualified supply of the active ingredients Chamomile and Passion Flower from Jiaherb and Euromed respectively (Also refer to Annex 8 §2).				
	2nd Response date: 1e We have evaluated Euromed questionnaire and attached in the folder 1f We have evaluated Vasa Pharm questionnaire and attached in the folder 1i Because of the COVID, we experienced a period of shutdown. So we just took the sample and sent for testing. Amended sample submission forms and sample submission form were attached	13/8/21	**Review 2** The supplier questionnaires for key suppliers have been reviewed and accepted for the vendor approval program. Additional ID testing requested for Magnesium Citrate, Chamomile and Passion Flower to support incoming material assessment. **Supply of starting materials will be reviewed at the next reinspection.**	Y

Not reviewed as Supplier Approval process about to change (guidance from TGA)

Major deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
2. The requirements of Annex 15 §1.1 that all qualification and validation activities should be planned and take the life cycle of facilities, equipment, utilities, process and product into consideration were not fully met. For example: a. Validation Master Plan VAL001 had not been updated for manufacture of tablets and powders. b. There was no VAL001 Appendix B available for process validation grouping. c. There was no protocol for the temperature mapping conducted in the warehouse in February 2021 (Also refer to Annex 15 §2.4). d. The -40°C walk-in freezer had not been considered for mapping studies to demonstrate uniformity of temperature throughout the unit (Also refer to Annex 15 §5.9). e. The Clean in Place (CIP) program was not referenced or defined in the Cleaning Study conducted on the 1000L cooking tank (Also refer to Annex 15 §10.4). f. Test method validation for Magnesium Content by ICP-OES (HW-AMVP-011) was performed on a hard shell capsule product (Dr Nature) with no	Please note : CAPA plan required as evidence for critical and major deficiencies that includes root cause analysis, corrective action/s to the root cause, preventative action/s to the root cause, corrections to observed examples, and due date for completion of actions. See headings below to be used for the response Response date: 15/07/2021 Identified Root Cause: Update of VMP was not up to date. Requirement on freezer temperature was not clearly given when production was producing food product. So the temperature mapping was missing. Method validation of sleep was not performed on proper placebo which should be same as actual formula. Corrective action/s to the Root Cause: VAL001 has been updated to include new production line. Temperature monitoring were performed and reported. Proper placebo has been provided to QC and the validation is ongoing. Preventative action/s to the Root Cause: The time for conducting the data into report will be shortened.	30/07/2021	OK 2a) VAL001 updated for manufacture of tablets and powders. **VMP will be reviewed at the next reinspection.** 2b) The correction provided does not address availability of VAL001 Appendix B for process validation grouping. Please provide 2nd response. 2c) It is acknowledged a protocol for the temperature mapping conducted in the warehouse has been generated. Please provide a conclusion as to the acceptability of the study in a 2nd response. 2d) Please provide a conclusion as to the acceptability of the freezer study in a 2nd response.	p13a Y - 2a, 2f, 2g. N - 2b, 2c, 2d, 2e.

Major deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
justification for how this validated the Vmores Sleep product testing (Also refer to Clause 6.15). g. Microbiology method validation (V-MIC-PDT-0052) was conducted on a Vmores Sleep placebo product that did not include herbal components (Also refer to Clause 6.15).	More communication between QA, QC and RND will be helpful for the validation in the future. Corrections to observed examples: SOP VAL0001 has been updated. Temperature monitoring report for freezer is done. Temperature monitoring for warehouse protocol is done. Report will be finalized soon. Method validation are ongoing, still need some time.		2e) The correction provided does not address definition of CIP program. Please provide 2nd response. 2f & g) Method validations using representative samples being progressed. **Test method validation will be reviewed at the next reinspection.**	chem mth valid acceptable p2
	2nd Response date: 2b Updated VMP with appendix B is attached 2c Filled report for warehouse is attached 2d Filled PQ for freezer and a Statement from RND were attached 2e Cleaning Validation report is updated.	13/8/21	**Review 2** 2b) VMP appendix B cited as updated for process validation. 2c) Warehouse mapping (summer study) has been summarised in a qualification report. **The recommendations from warehouse study will be reviewed at the next inspection.** 2d) Mapping study for the -40°C walk-in freezer has been conducted to demonstrate an acceptable temperature profile. 2e) CV report has been amended to clarify validation CIP program.	Y

issue detected with monitoring p8

Major deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
3. The requirements of Annex 15 §11.4 that quality risk management should be used to evaluate planned changes to determine the potential impact on product quality, pharmaceutical quality systems, documentation, validation, regulatory status, calibration, maintenance and on any other system to avoid unintended consequences and to plan for any necessary process validation, verification or requalification efforts were not fully met as evidenced by the following: a. Change controls were not fully effective in detailing the actions required in order to control the implementation of change: i. CC20035 for the facility expansion did not state if change was major/minor. There was no implementation plan available in the change control. This was a significant site expansion project for new production lines/areas, which was in progress at the time of inspection. In addition, there was no risk assessment conducted to determine any impact on current production activity at the site. ii. CC20043 for the introduction of Vmores Sleep did not include the	Please note : CAPA plan required as evidence for critical and major deficiencies that includes root cause analysis, corrective action/s to the root cause, preventative action/s to the root cause, corrections to observed examples, and due date for completion of actions. See headings below to be used for the response Response date: 16/07/2021 Identified Root Cause: Some of the changes were not well organized at the beginning, jobs were recorded after it is done instead of well planned at the beginning. Corrective action/s to the Root Cause: In the SOP QA0005 Change Control Procedure, we added time frame and follow-up task to make the plan more organized. QAF006 Change Control Form has been updated to perform the task. Preventative action/s to the Root Cause: A training on the new procedure will be given to all the staff who needs to raise a change control, so that they can manage the plans better. Corrections to observed examples: SOP QA0005 has updated the Risk Acceptable Criteria to match the risk matrix.		**Review 1** It is acknowledged that SOP QA0005 has been updated and improvements implemented to change control system. The response does not provide sufficient detail on CC20035 for the site expansion particularly in relation to risk assessment and project management. Please provide this in a 2nd response.	N

Major deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
validation, stability, documents and training activity required to support the product introduction. iii. CC21020 for the Vmores Sleep formulation change did not have QA approval for implementation. b. Target dates were not assigned to action items or change controls to manage the progression and completion of changes.	For CC20035, we can not change the scale, but we have updated the scale of change into QAF006. For CC20043, Validation and stability are ongoing. We have added these into the job list. CC21020 is closed. SOP QA0005 has updated the time frame. The expected date is added to QAF006.			
	2nd Response date: 3a(i) As I mentioned, this change control was raised last year, we did not put scale into consideration. Now we have added a column in the register for change scale. What I can do to the existing change control is adding a definition of the change scale. If needed, I can close the change control and raise a new one using new change control format, which I sent.	20/8/21	**Review 2** It is accepted that the scale of the CC has been added. A detailed project plan should be included as an attachment to the CC. **Change management will be reviewed at the next reinspection.**	Y

p2 of notes
Minor comments

Other deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
4. The requirements of Clause 2.11 that newly recruited personnel should receive training appropriate to the duties assigned to them, continuing training should also be given, and its practical effectiveness should be periodically assessed and that training programmes should be available, approved by either the head of Production or the head of Quality Control, as appropriate was not fully met as evidenced by: a. The training program for release for supply qualification was not outlined in the Quality Management System. Training was limited to reading of the QA0029 SOP with no consideration of conducting an associated test or assessment of trainees' ability to perform RFS of all relevant dosage forms etc. b. The training system did not adequately cover practical effectiveness of training activity. For example, there was no practical training provided for the Freeze-Drying equipment and training was limited to procedural training by QA who were not the subject matter experts for this equipment/process.	For the deficiencies categorised as 'other', a CAPA plan is not required; however, the response date, and the correction and due date /completion date are required to be provided. See headings below to be used for the response Response date: 17/06/2021 Corrections to observed examples: Quality Manual has been updated with RFS training SOP QA0004 has been updated to mention induction training is performed in the first week of employees. On-the-job training will be proved by attaching relevant work record, such as batch document copy and document prepared or signed. However, the training is ongoing, we can only collect these information step by step.	17/06/2021	The training system has been updated to formalise RFS training and OTJ training. **Training will be reviewed at the next reinspection.**	Y

Review @ p14
Not fully implemented

Other deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
c. There was no timeframe stated for the completion of induction training of new employees.				

Other deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
5. The requirements of the Clause 1.4 (xiv) that a Pharmaceutical Quality System appropriate for the manufacture of medicinal products should ensure that appropriate level of root cause analysis should be applied during the investigation of deviations, suspected product defects and other problems and appropriate corrective actions and/or preventive actions (CAPAs) should be identified and taken in response to investigations, with the effectiveness of such actions monitored and assessed were not fully met as evidenced by: a. In relation to the Quality Incident Deviation Report (QIDR) system: i. The rejected batch of Vmores Sleep (H00603) was not subject to a formal investigation/QIDR. There were no actions recorded to show root cause analysis and CAPA to address the formulation issues that resulted in the batch rejection. ii. SOP QA0006 did not clearly reference the QIDR register (R4). iii. QA0006 did not adequately describe the planned and unplanned deviation process. The QIDF did not differentiate between these deviation types.	For the deficiencies categorised as 'other', a CAPA plan is not required; however, the response date, and the correction and due date /completion date are required to be provided. See headings below to be used for the response Response date: 15/07/2021 Corrections to observed examples: SOP QA0006 has been updated to include R4 as reference. Planned/Unplanned deviation has been added. QAF007 has been updated to include Planned/Unplanned deviation. Time frame has been added to SOP QA0013 and the risk assessment has been updated.	01/07/2021	Review 1 It is acknowledged that SOP QA0006 and QA0013 have been updated to address the deficiencies. The response does not provide sufficient detail on rejected batch of Vmores Sleep (H00603) and how this has been assessed in the QMS. Please provide this in a 2nd response.	N

Other deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
b. In relation to the complaint investigation process SOP QA0013: i. There was an inconsistent approach for risk assessment of customer complaints. Critical, major and minor complaints were defined in QA0013 but did not occur in risk matrix, which used low, medium, high and extreme levels of risk. It was not clear how the risk levels aligned with the complaint categories. ii. The timelines for actions and closure of complaint investigations were not defined (Also refer to Clause 8.14).				
	2nd Response date: 5a(i) A new deviation QID21014 was raised to cover this batch.	12/8/21	**Review 2** The investigation, assessment and corrections for rejected batch of Vmores Sleep (H00603) has been completed in QID21014. **Deviation management will be reviewed in the next reinspection.**	Y

Acceptable
Reviewed
pG-7

Other deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
6. The requirements of Clause 4.29 that there should be written policies, procedures, protocols, reports and the associated records of actions taken or conclusions reached, where appropriate, for environmental monitoring were not fully met. For example; a. Pressure differentials from the warehouse to material transfer airlock interface were not routinely monitored. b. The control parameter of temperature was not recorded in the batch record (MWO) for the -40°C freezer step. c. There were no alert limits established for water or environmental monitoring programs. d. There was no requirement to heighten the monitoring of water or the environment in the event of an Out of Specification (OOS). e. Microbial identification was not required for OOS reported on water or environmental monitoring. f. The trend reporting of water and environmental data was not formalised by procedure.	For the deficiencies categorised as 'other', a CAPA plan is not required; however, the response date, and the correction and due date /completion date are required to be provided. See headings below to be used for the response Response date: 15/07/2021 Corrections to observed examples: To make it easier to be checked, the magnehelic gauges for airlock have been relocated to production side. New logbooks have been prepared and set in airlocks. Production operators are now responsible for recording. RND has provided a study report on freezer requirement and a temperature mapping protocol is done for freezer. Alert limit has been added to SOP QA0018 Environmental monitoring procedure and SOP QA0044 Monitoring of Purified water. Requirement to heighten the monitoring frequency after OOS occurred has been added to SOP QA0018 and QA0044. Microbial identification has been added to SOP QA0018 and QA0044. Annual trending report mentioned in SOP QA0014, QA0018 and QA0044.	15/07/2021	6a) Pressure differential checks have been added to the airlock. **Room pressure monitoring systems will be reviewed at the next reinspection.** 6b) Freezing mapping study conducted. Temperature monitoring should be recorded during manufacture. 6c-e) Alert limits and OOS response activity added to the water and environmental monitoring program. **Water and environmental monitoring will be reviewed at the next reinspection.** 6f) Annual trending of water and environmental data updated into the QMS.	Y

On-going
minor issue
p8

Australian Government
Department of Health
Therapeutic Goods Administration

Manufacturing Quality Branch

Close Out Record - Final

Other deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
7. The requirements of Clause 1.10 and 1.11 pertaining to product quality reviews; that such reviews should normally be conducted and documented annually and quality reviews may be Pharmaceutical Quality System grouped by product type e.g. solid dosage forms, liquid dosage forms, sterile products, etc. where scientifically justified, were not fully met. For example: a. There were no timelines associated with the completion of Periodic Product Reviews (PQRs) in SOP QA0028. b. There was no grouping strategy for the PQRs. It was unclear if PQRs were required for each product.	For the deficiencies categorised as 'other', a CAPA plan is not required; however, the response date, and the correction and due date /completion date are required to be provided. See headings below to be used for the response Response date: 06/07/2021 Corrections to observed examples: Updated SOP QA0028 to include PQR period Added detail of grouping and OOT	06/07/2021	Updates have been completed for SOP QA0028 for the management of PQRs. **Product Quality Reviews will be included in the next reinspection.**	Y

Reviewed p5 - On-going issues

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Manufacturing Quality Branch

Close Out Record - Final

Other deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
8. The requirements of Clause 4.1 that complex systems need to be understood, well documented, validated, and adequate controls should be in place were not fully met. For example: a. The administration SOP-QC-0023 for this computerised system did not adequately define the users and their management in the laboratory (Also refer to Annex 11 §12). b. The computerised systems register did not include the version number of the GxP systems. c. The Microbiology Lab used MSTEAMs for access to controlled forms. There was no evidence this system was validated and analysts could print multiple copies of test forms, which were not traceable.	For the deficiencies categorised as 'other', a CAPA plan is not required; however, the response date, and the correction and due date /completion date are required to be provided. See headings below to be used for the response Response date: 15/07/2021 Corrections to observed examples: SOP-QC-0023 will be updated to define users and management. Version number of systems have been added to the CSR Micro lab has issued one logbook to record the job.	30/07/2021	Corrections have been made for the control of these computerised systems. Use of MSTEAMs has been discontinued in Microbiology Lab and logbook has been introduced. **Computerised systems will be reviewed at the next reinspection.**	Y

Pretty good. Comments to staff on formalising site based verification p13a

Other deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
9. The requirements of Clause 1.8 (iv) that instructions and procedures are written in an instructional form in clear and unambiguous language, specifically applicable to the facilities provided was not fully met as evidenced by: a. The Quality Manual stated that GMP documents were retained for 6 years. This conflicted with the retention times cited in QA0001 for Document Control i.e. 5 years. b. The rework procedure SOP QA0024 did not clearly define what processes were eligible for rework i.e. freeze-dried bulk product could not be reprocessed once freeze drying had occurred. c. The mock recall form QAF011 was not clearly linked to the SOP QA0010. d. The media preparation sheet (QCF) in the Microbiology laboratory incorrectly referenced SOP-MIC-0016. e. The stability program did not state the frequency of stability testing i.e. minimum of 1 batch per year (Also refer to Clause 6.32). f. The autoclave programs for media sterilisation in the Microbiology laboratory were not clearly defined in the associated SOP-MIC-0047.	For the deficiencies categorised as 'other', a CAPA plan is not required; however, the response date, and the correction and due date /completion date are required to be provided. See headings below to be used for the response Response date: 15/07/2021 Corrections to observed examples: The Quality Manual has been updated according to SOP QA0001. SOP QA0024 has been updated with the detail of eligible type of rework. SOP QA0010 has been updated with QAF011 as reference. QCF reference and SOP-MIC-0047 will be updated and approved in one week. SOP QA0042 has been updated with minimum stability batch required annually.	23/07/2021	The relevant documents will be updated to reflect activities being performed. The will improve consistency within the QMS.	Y ✓

Other deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
10. The requirement of Clause 8.30 that the effectiveness of the arrangements in place for recalls should be periodically evaluated to confirm that they remain robust and fit for use was not fully met as the mock recall conducted in 2020 did not incorporate stock reconciliation of the recalled product.	For the deficiencies categorised as 'other', a CAPA plan is not required; however, the response date, and the correction and due date /completion date are required to be provided. See headings below to be used for the response Response date: 07/07/2021 Corrections to observed examples: QAF011 Product Recall/Withdrawal Report Form is updated to include the reconciliation.	07/07/2021	Stock reconciliation has been added to improve the mock recall process.	Y ✓
11. The requirement of Clause 5.57 that checks should be made to ensure that any electronic code readers, label counters or similar devices are operating correctly was not fully met as the performance checks on the label counter were limited to annual calibration only.	For the deficiencies categorised as 'other', a CAPA plan is not required; however, the response date, and the correction and due date /completion date are required to be provided. See headings below to be used for the response Response date: 16/06/2021 Corrections to observed examples: A logbook following the content of new form QAF076 is prepared for performing weekly check (if label counter is to be used).	16/06/2021	A weekly calibration check has been introduced for the label counter to ensure accuracy.	Y ✓

Other deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
12. The requirement of Clause 5.13 that labels applied to containers, equipment or premises should be clear, unambiguous and in the company's agreed format was not fully met as evidenced by: a. The QC balances external calibration labels did not align with the annual requirement in SOP QC 0032. b. There was no status label affixed to the 'unqualified' water activity meter in the QC laboratory.	For the deficiencies categorised as 'other', a CAPA plan is not required; however, the response date, and the correction and due date /completion date are required to be provided. See headings below to be used for the response Response date: 08/07/2021 Corrections to observed examples: Annual calibration was performed, and stickers attached. QA has combined the calibration registers of Chemical and Micro lab. Monthly check will be performed to cover all the areas. QC has attached 'Do not use, Instrument Under Installation' label on water activity meter according to the SOP.	08/07/2021	Corrections have been made for labelling of QC equipment.	Y ✓

Other deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
13. The requirements of Clause 2.8(i) that the head of Quality Control generally has the following responsibilities; to approve or reject, as he/she sees fit, starting materials, packaging materials, intermediate, bulk and finished products was not met in the job description for QA Team Leader (draft), which, was proposed as the head of Quality Control.	For the deficiencies categorised as 'other', a CAPA plan is not required; however, the response date, and the correction and due date /completion date are required to be provided. See headings below to be used for the response Response date: 02/07/2021 Corrections to observed examples: Job Description of QA Team Leader has been finalized to contain the duty of release and reject for raw/packaging material and bulk/finish product.	02/07/2021	QA Team Lead job description has been updated to incorporate release/reject of materials and product.	Y ✓
14. The requirement of Clause 5.66 that rejected materials and products should be clearly marked as such and stored separately in restricted areas was not fully met as the rejected materials and returned goods section of the warehouse were not restricted access.	For the deficiencies categorised as 'other', a CAPA plan is not required; however, the response date, and the correction and due date /completion date are required to be provided. See headings below to be used for the response Response date: 17/05/2021 Corrections to observed examples: Designated reject and returned goods area have been relocated in warehouse 3, and gates are installed to restrict the access.	17/05/2021	A secure reject area has been introduced in the warehouse.	Y ✓

CAPA review 2022 for inspection

Document 13

Manufacturer name:	GMP Pharmaceuticals Pty Limited
Manufacturer address:	60 Huntingwood Drive, Huntingwood, NSW 2148
Inspection type:	Licence Variation
Inspection dates:	5 – 6 May 2022
Inspectors:	s22 [redacted]
Inspection standard:	PIC/S Guide to Good Manufacturing Practice for Medicinal Products (PE009-14)

Major deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
1. The requirements of Annex 15 §11.4 that quality risk management should be used to evaluate planned changes to determine the potential impact on product quality, pharmaceutical quality systems, documentation, validation, regulatory status, calibration, maintenance and on any other system to avoid unintended consequences and to plan for any necessary process validation, verification or requalification efforts were not fully met as evidenced by the following: a. Change Control, CC21065 for the introduction of new processes i.e. tablet coating, wet granulation and hard shell capsules, was not appropriately managed as required actions were not adequately recorded or controlled: i. The approval to proceed on 14/01/2022 was retrospective as facility expansion, equipment purchase/delivery and validation	Please note: CAPA plan required as evidence for critical and major deficiencies that includes root cause analysis, corrective action/s to the root cause, preventative action/s to the root cause, corrections to observed examples, and due date for completion of actions. See headings below to be used for the response Response date: 27/05/2022 Identified Root Cause: 1. QA supervisor was reviewing but not following properly. The change control CC20035 was raised for multiple tasks including Sachet, Tablet and Dairy line, but it was suggested to be separated. When we decided to raise a separate change control (CC21065), some of the actual jobs have been started already following CC20035. 2. The change controls of upgrading compressed air system (CC21028) and upgrading RO water system (CC21029) were raised in May 2021, when some of the key persons were working from home and meetings were held online. Also, the project was delayed due to the virus issue. When the jobs were done, CC21065 was already raised for the project, so we thought it should be	27/05/2022	It is acknowledged that working from home/online meetings may have adversely impacted on the documentation of change control activities It is not clear if the relevant SOP will be updated to include the preventative actions proposed. A monthly QA review will be implemented but it is not clear if target dates are being assigned to change controls to further track their progression. Please provide a 2nd response clarifying the change control improvements	N

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Major deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
preparation were in progress at that time. ii. There was no link or reference to CC20035 for the facility expansion that was previously approved for implementation. iii. CC21065 was limited to equipment qualification and training and did not adequately consider upgrades to critical utilities, QMS requirements and the GMP licence updates required for this change. b. There was ineffective management for change controls as target dates were not always assigned to action items or change controls to manage the completion of changes. For example, CC21028 for compressed air upgrade and CC21029 for RO Water upgrade had been raised in May 2021 but had not been progressed even though both systems had been upgraded and requalified.	covered in the project and missed those two change controls. Corrective action/s to the Root Cause: 1. CC21065 will add CC20035, CC21028 and CC21029 as reference. 2. CC21028 and CC21029 will be filed and closed. Preventative action/s to the Root Cause: 1. Monthly review of change control is delegated to one of the QA Officer, who will follow-up the pending change control until it is closed. 2. Change controls linked to existing change controls should be mentioned in supporting documents. 3. A review of related change controls should be performed when sub-change control is raised. Corrections to observed examples: Adding CC20035, CC21028 and CC21029 as reference in CC21065. Finalized CC21028 and CC21029.			

Major deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
	2nd Response date: 24/06/2022 Preventative action/s to the Root Cause: SOP QA0005 Change Control Procedure has been updated to include the CAPA mentioned in the previous reply. Responsibility of document controller has been added and monthly check detail has been clarified.	24/06/2022	CAPAs proposed have been formalised in the change management procedures. **Effective change management will be revised at the next reinspection.** Acceptable p2 of notes	Y

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Other deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
2. The requirements of Annex 15 §1.1 that all qualification and validation activities should be planned and take the life cycle of facilities, equipment, utilities, process and product into consideration were not fully met. For example: a. The VMP (v4) had not been updated for hard shell capsule and granule dosage forms. b. The VMP did not outline the process for handling deviations that occurred during validation. c. There was no methodology or acceptance criteria outlined for active air and swab sampling conducted for the HVAC PQ in the tablet manufacturing area. The protocol did not reference the routine SOP for environmental monitoring. d. The action limit 1000cfu/m³ applied to compressed air monitoring in PQ testing was not justified in relation to direct product contact zones. e. The computerised system validation for the coating machine did not adequately test the following critical attributes: i. User security such as locking of system following unauthorised login attempts. In addition, SOP	For the deficiencies categorised as 'other', a CAPA plan is not required; however, the response date, and the correction and due date /completion date are required to be provided. See headings below to be used for the response Response date: 27/05/2022 Corrections to observed examples: VMP has been updated to include hard shell capsule and granules. Handling Validation deficiency has been added. In TBUPQ004 for Tablet line HVAC, acceptance criteria for air sampling and swab testing added. Reference of EM SOP added. Room condition and air flow drawing added. TBIOQ006 IOQ for coating machine-software has been updated to include the verification of user security, user level, audit trial report and data backup.	27/05/2022	**Review 1:** It is acknowledged that updates have been applied to VMP, HVAC PQ and coating machine CSV. It is not clear how the action limit 1000cfu/m3 applied to compressed air monitoring in PQ testing was justified in relation to direct product contact zones. Please provide an additional response for 2d.	Y - 2a,2b,2c,2e N - 2d

Other deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
PTB0009 for the coating machine did not outline administration of the system i.e. control of users (Also Annex 11 §12). ii. Audit trail verification. Furthermore, SOP PTB0009 did not outline the use of audit trail (Also Annex 11 §9). iii. Data storage/back-up (Also Annex 11 §7).				
	2nd Response date: 24/06/2022 Corrections to observed examples: SOP QA0018 Environmental Monitoring Procedure has updated all the compressed air limit from 1000cfu/m³ to 200cfu/m³	24/06/2022	The new limits for compressed air monitoring have been included in the relevant SOP. This limit provides a more appropriate measure of air quality for compressed air in contact with production.	Y

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Other deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
3. The requirement of Clause 3.41 that measuring, weighing, recording and control equipment should be calibrated and checked at defined intervals by appropriate methods, and adequate records of such tests should be maintained, was not fully met as evidenced by: a. There was no calibration label on the dispensary scales CAL620 b. The bubble level was not centred for weighing equipment CAL620 in the in-process testing room.	For the deficiencies categorised as 'other', a CAPA plan is not required; however, the response date, and the correction and due date /completion date are required to be provided. See headings below to be used for the response Response date: 27/05/2022 Corrections to observed examples: Calibration label has been sticked on, and photo has been taken. SOP QA0032 Calibration of Scales is updated to emphasis adjusting the balance to make the bubble in the middle. Training for operators is ongoing.	27/05/2022	Actions have been taken to clearly identify calibration status of CAL620 and to apply levelling of the weighing equipment. Training conducted accordingly for operators. **Balance checks will be reviewed at the next reinspection.**	Y

OK – Reviewed on Tour

Other deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
4. The requirement of Clause 3.42 that fixed pipework should be clearly labelled to indicate the contents and, where applicable, the direction of flow was not fully met as pipework (water etc.) in the wet granulation area was not labelled to signify direction of material flow.	For the deficiencies categorised as 'other', a CAPA plan is not required; however, the response date, and the correction and due date /completion date are required to be provided. See headings below to be used for the response Response date: 27/05/2022 Corrections to observed examples: Direction signs for pipelines have been sticked on the pipes and photos have been taken.	27/05/2022	Photos have been provided of the pipework labels applied to address this deficiency. No further action required.	Y

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Other deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
5. The requirement of Clause 4.29 that there should be written policies, procedures, protocols, reports and the associated records of actions taken or conclusions reached for maintenance, cleaning and sanitation was not fully met as there was no procedure for cleaning of some product contact equipment i.e. cleaning of transfer chute in dispensing from sieving to IBC.	For the deficiencies categorised as 'other', a CAPA plan is not required; however, the response date, and the correction and due date /completion date are required to be provided. See headings below to be used for the response Response date: 27/05/2022 Corrections to observed examples: SOP PTB0008 has been updated to include inspection and cleaning procedure of cloth and silicon sleeves used for connecting sieve machine and blender bin.	27/05/2022	SOP PTB0008 has been updated to adequately describe the cleaning procedure of cloth /silicon sleeves used for connecting sieve machine and blender bin. This must also be considered in cleaning validation studies. **Equipment cleaning will be reviewed at the next reinspection.**	Y

All equipment clean + stored appropriately

Other deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
6. The requirement of Annex 11 §4.3 that an up to date listing of all relevant systems and their GMP functionality (inventory) should be available was not fully met as there was no register for GMP computerised systems used at the site.	For the deficiencies categorised as 'other', a CAPA plan is not required; however, the response date, and the correction and due date /completion date are required to be provided. See headings below to be used for the response Response date: 27/05/2022 Corrections to observed examples: The computerized system used in coating machine and wet granulation machine are validated with equipment but not added in the register. CSR will be updated to include. 2nd Response date: 24/06/2022 Corrections to observed examples: SOP VAL0004 Computerised System Validation Master Plan has been updated to clarify the register number of Computerised System Register. SOP QA0016 Registers has been updated to include R28 Computerised System Register.	31/05/2022 24/06/2022	**Review 1** It is acknowledged that computerized systems used in coating machine and wet granulation machine are validated. However please provide information on the register for computerised systems (CSR) – it is not clear from this response if the CSR is a controlled document with relevant format to meet Annex 11 requirements. R28 Computerised System Register has been created and introduced into the QMS and will be governed by CSV Master Plan.	N Y

Under implementation
- reviewed change management

Other deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
7. The requirement of Annex 11 §13 that all incidents, not only system failures and data errors, should be reported and assessed; and the root cause of a critical incident should be identified and should form the basis of corrective and preventive actions, was not fully met as SOP PTB0009 for the coating machine did not outline handling of equipment failure or alarms.	For the deficiencies categorised as 'other', a CAPA plan is not required; however, the response date, and the correction and due date /completion date are required to be provided. See headings below to be used for the response Response date: 27/05/2022 Corrections to observed examples: SOP PTB0009 is updated to include User levels, handling of alarm alert, equipment trouble shooting and Reports function (equivalent to audit trial).	27/05/2022	SOP PTB0009 for the coating machine has been updated for handling of equipment failure or alarms. **Handling of production alarms will be reviewed at the next reinspection.**	Y

Reliant on staff to notify prod. manager
No check on audit trail for unreported alarms.
② – P11

Other deficiency	Manufacturer's response	Proposed completion date	Inspector's comments	Response accepted Y/N
8. The requirements of Annex 15 §4.1 that equipment, facilities, utilities and systems should be evaluated at an appropriate frequency to confirm that they remain in a state of control was not fully met as routine sampling of the purified water system was monthly but this frequency was not justified given the recent qualification and lack of historical data available.	For the deficiencies categorised as 'other', a CAPA plan is not required, however, the response date, and the correction and due date /completion date are required to be provided. See headings below to be used for the response. Response date: 27/05/2022 Corrections to observed examples: SOP QA0018 Environmental Monitoring Procedure and SOP QA0044 Monitoring of Purified Water have been updated to include weekly TVAC testing on five critical points. Sampling activity will start from 23rd May 2022.	27/05/2022	Weekly monitoring of the purified water system has been implemented which will provide assurance around the water quality and performance of the PW system during initial manufacture at the site. **Purified water will be reviewed at the next reinspection.** PW under good control	Y

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TGA to complete		
Lead inspector e-sign off after receipt and acceptance of CAPA plan	**Name:**	**Date:**
Signed and authorised by:	Emmett Broderick	3/07/2022

From: s22 [redacted]
To:
Cc:
Subject: TGA Post Inspection Letter - GMP Pharmaceuticals - Huntingwood - April 2025 [SEC=OFFICIAL]
Date: Friday, 11 April 2025 2:27:08 PM
Attachments: TGA Post Inspection Letter - GMP Pharmaceuticals - Huntingwood - April 2025.pdf
TGA Close Out Record - GMP Pharmaceuticals - Huntingwood - April 2025.docx
image001.png
image002.png
image003.png
image004.gif
image005.png
image006.png
image007.jpg

Dear s22 [redacted],

Please find attached the Post Inspection Letter (PIL) for the surveillance re-inspection that took place at GMP Pharmaceuticals Huntingwood premises on 3 – 4 April 2025.

I have also included a pre-populated Close Out Record, which you can use to record your responses.

As discussed at the closing meeting, you are requested to provide a description of your proposed corrective actions and a timeframe for completion if unable to complete them prior to responding to me. Objective evidence is **not** required for the deficiencies identified.

You are requested to provide your response to me by **9 May 2025**.

Thank you again for your assistance and hospitality throughout the inspection. I look forward to reviewing your response once it becomes available in the next month or so. Please do not hesitate to contact me should you need clarification regarding the inspection or the PIL.

Could you please send me a brief email as soon as you receive this message to let me know the attachments arrived to you.

Regards
s22 [redacted]

s22 [redacted] (she/they)
Senior Inspector
Inspections and Compliance | Manufacturing Quality Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s22 [redacted]@health.gov.au
Location: Remote
Post: PO Box 100, Woden ACT 2606 Australia
www.tga.gov.au

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This is general information given to you without prejudice; it is not binding on the TGA and you should get your own

independent legal advice to ensure that all of the legislative requirements are met

---

From: s22
Sent: Friday, 4 April 2025 1:55 PM
To: s22 @gmp.com.au>
Cc: s22 @gmp.com.au>
Subject: TGA Inspection closing meeting summary - GMP Pharmaceuticals - Huntingwood - April 2025 [SEC=OFFICIAL]

Dear s22 ,

Please find attached the closing meeting summary for the inspection.

Regards
s22

s22 (she/they)
Senior Inspector
Inspections and Compliance | Manufacturing Quality Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s22 @health.gov.au
Location: Remote
Post: PO Box 100, Woden ACT 2606 Australia
www.tga.gov.au

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met

---

From: s22 gmp.com.au>
Sent: Wednesday, 2 April 2025 3:12 PM
To: s22 @health.gov.au>
Cc: s22 @gmp.com.au>
Subject: Re: Inspection plan for Huntingwood TGA Audit [SEC=OFFICIAL]

Hi s22

Well received. Thank you. See you tomorrow.

s22 | QA Manager

P: s22 | M: s22
E: s22 @gmp.com.au | www.gmp.com.au

14 Amax Avenue,
GIRRAWEEN

60 Huntingwood Drive,
HUNTINGWOOD

New South Wales 2145 New South Wales 2148

Australia Australia

Global Headquarters
60 Huntingwood Drive, Huntingwood NSW 2148

From: s22 [redacted] @health.gov.au>
Sent: 02 April 2025 14:53
To: s22 [redacted] @gmp.com.au>
Cc: s22 [redacted] @gmp.com.au>
Subject: Inspection plan for Huntingwood TGA Audit [SEC=OFFICIAL]

Dear s22 [redacted]

My apologies for attaching the incorrect version of the plan to my previous email.

Please use the one attached here for this week's inspection.

Regards
s22 [redacted]

s22 [redacted] (she/they)
Senior Inspector
Inspections and Compliance | Manufacturing Quality Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s22 [redacted] @health.gov.au

Location: Remote
Post: PO Box 100, Woden ACT 2606 Australia
www.tga.gov.au

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met

---

From: s22
Sent: Wednesday, 2 April 2025 2:48 PM
To: s22 gmp.com.au>
Cc: s22 @gmp.com.au>
Subject: RE: Required Documents for Huntingwood TGA Audit [SEC=OFFICIAL]

Dear s22

Please find attached the plan for this week's inspection. We can discuss the plan during the opening meeting and adjust as required by staff availability.

I will be at the Huntingwood site by 9.30 AM tomorrow.

Regards
s22

s22 (she/they)
Senior Inspector
Inspections and Compliance | Manufacturing Quality Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s22 @health.gov.au
Location: Remote
Post: PO Box 100, Woden ACT 2606 Australia
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---

From: s22
Sent: Tuesday, 25 March 2025 2:20 PM
To: s22 @gmp.com.au>
Cc: s22 @gmp.com.au>
Subject: RE: Required Documents for Huntingwood TGA Audit [SEC=OFFICIAL]

Dear s22 ,

Thank you providing the requested documents. All are well received.

Regards
s22

s22 (she/they)
Senior Inspector
Inspections and Compliance | Manufacturing Quality Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s22 @health.gov.au
Location: Remote
Post: PO Box 100, Woden ACT 2606 Australia
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This is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met

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From: s22 @gmp.com.au>
Sent: Monday, 24 March 2025 5:10 PM
To: s22 @health.gov.au>
Cc: s22 @gmp.com.au>
Subject: Required Documents for Huntingwood TGA Audit

Hi s22 ,

Please find required documents for Huntingwood site audit.
Our production manager, s22 , just left GMP the week before last week, so our site master file did not capture the change. Related change control is attached.
Please feel free to contact me if you have any question. Thank you.

s22 | QA Manager
s22
gmp.com.au |
www.gmp.com.au
14 Amax Avenue, 60 Huntingwood

Drive,
GIRRAWEEN HUNTINGWOOD

New South Wales 2145 New South Wales 2148

Australia Australia

Global Headquarters
60 Huntingwood Drive, Huntingwood NSW 2148

Close Out Record

Manufacturer name:	GMP Pharmaceuticals Pty Limited
Manufacturer address:	60 Huntingwood Drive Huntingwood NSW 2148
Inspection type:	Surveillance re-inspection
Inspection date/s:	3 – 4 April 2025
Inspector/s:	s22 [redacted]
Inspection standard:	PIC/S Guide to Good Manufacturing Practice for Medicinal Products (PE009-16)

Major Deficiencies

Please Note: CAPA plan required as evidence for major deficiencies that includes root cause analysis, corrective action/s to the root cause, preventative action/s to the root cause, corrections to observed examples, and due date for completion of actions. See headings below to be used for the response

Major Deficiency:

1. The requirement of Clause 1.10 that regular periodic or rolling quality reviews of all authorised medicinal products, including export only products, should be conducted with the objective of verifying the consistency of the existing process, the appropriateness of current specifications for both starting materials and finished product, to highlight any trends and to identify product and process improvements; and these product quality reviews (PQRs) should normally be conducted and documented annually, were not fully met. For example, there were no formal processes in place to ensure PQRs were available for all authorised medicinal products manufactured at site, and to ensure PQRs were conducted annually (or every 2 years for low volume products). The inspector noted that the available PQRs may represent the full product range; however, GMP Pharmaceuticals approved process was to conduct individual, product based PQRs, rather than using a grouped product approach.

Response Date:

Date of completion:

Identified Root Cause:

Corrective action/s to the Root Cause:

Corrections to observed examples:

Inspector's Review:

A similar deficiency was recorded at the previous routine re-inspection conducted in May 2021.

Response accepted?

Follow-up required at next inspection: Yes/No

Major Deficiency:

2. The requirements of Clause 2.11 that newly recruited personnel should receive training appropriate to the duties assigned to them, continuing training should also be given, and its practical effectiveness should be periodically assessed, were not fully met. For example, processes for recording the effectiveness of on-the-job training had been formalised into procedures; however, the planned checklists for recording on-the-job training activities were still being developed and no records of on-the-job training were available.

Response Date:

Date of completion:

Identified Root Cause:

Corrective action/s to the Root Cause:

Corrections to observed examples:

Inspector's Review:

A similar deficiency was recorded concerning on-the-job training at previous routine re-inspections, including that conducted in May 2021

Response accepted?

Follow-up required at next inspection: Yes/No

Other deficiencies
Please note : A CAPA plan is required as evidence for "other" deficiencies. As a minimum this should include corrections to observed examples, and due date for completion of actions. A deficiency may be "other" either because it is judged as minor, or because there is insufficient information to classify it as major or critical, therefore manufacturers are encouraged to perform root-cause-analysis to determine the severity and extent of the deficiency and determine appropriate actions to address the deficiency. See headings below to be used for the response.

Other Deficiency:

3. The requirements of Annex 15 §10.9 that where campaign manufacture is carried out, the impact on the ease of cleaning at the end of the campaign should be considered and the maximum length of a campaign (in time and/or number of batches) should be the basis for cleaning validation exercises was not fully met. For example, cleaning validation protocols associated with the extension of campaign manufacturing activities, outlined in Quality Incident report, QID 24124, did not specify hard to clean locations on equipment, which could be impacted by the extended campaign length, to ensure these were reviewed for visual cleanliness and microbiological build-up.

Response Date:

Date of completion:

Corrections:

Inspector's Review:

Response accepted?

Follow-up required at next inspection: Yes/No

Other Deficiency:

4. The requirements of Annex 15 §11.4 concerning change control, that quality risk management should be used to evaluate planned changes to determine the potential impact on product quality, pharmaceutical quality systems, documentation, validation, regulatory status, calibration, maintenance and on any other system to avoid unintended consequences, and to plan for any necessary process validation, verification or requalification efforts, had not been fully implemented. For example, new product introduction processes did not consistently evaluate the need for process validation, nor formally evaluate whether the new product should be included in the site's on-going stability program. For example, regarding Change Control CC24163 for the transfer of Wonderland Capsules from GMP Pharmaceuticals Girraween site to the Huntingwood site,
    a. CC24163 did not identify process validation as a requirement, nor was there an evaluation recorded to ensure the new product was represented by the existing process validation product groups.
    b. CC24163 did not evaluate the need for an on-going stability study for the new product. It is acknowledged that on-going stability for this product was underway at the Girraween site; however, this was not documented in the change control and it was unclear whether manufacturing processes at the Huntingwood site would be comparable to those used at the Girraween site.

Response Date:

Date of completion:

Corrections:

Inspector's Review:

Response accepted?

Follow-up required at next inspection: Yes/No

Other Deficiency:

5. The requirements of clause 3.19 that storage areas should be designed or adapted to ensure good storage conditions, [. . .] they should be clean and dry and maintained within acceptable temperature limits, and where special storage conditions are required (e.g. temperature, humidity) these should be provided, checked and monitored, were not fully met. For example, the warehouse temperature in the locations used for storage of gelatine capsule shells were not specifically monitored. The warehouse temperatures were monitored at the 'worst case' locations and temperature excursions were only actioned when temperatures were above 30 °C. There was no evidence available to demonstrate the storage locations for gelatine capsule shells would remain at or below 25 °C, as required by the special storage conditions of the material. The temperature records indicated the 'worst case' locations were above 25 °C (and below 30 °C) on multiple occasions during January and February 2025.

Response Date:

Date of completion:

Corrections:

Inspector's Review:

Response accepted?

Follow-up required at next inspection: Yes/No

Other Deficiency:

6. The requirements of clause 5.19 that cross-contamination should be prevented by attention to design of the premises and equipment as described in Chapter 3 of the PIC/S Guide, and this should be supported by attention to process design and implementation of any relevant technical or organizational measures, including effective and reproducible cleaning processes to control risk of cross-contamination, were not fully met. For example, wash bays on both the mezzanine level and ground floors of the Tableting/Dry Powder Suite were noted to have black residue on some horizontal surfaces within the wet areas of the wash bay. The residue was present in/on sealant between wall panels and floor coving, and upon multiple horizontal ledges around the wash bay enclosures.

Response Date:

Date of completion:

Corrections:

Inspector's Review:

Response accepted?

Follow-up required at next inspection: Yes/No

Other Deficiency:

7. The requirements of clause 5.21 regarding technical measures required to control risks for cross-contamination were not fully met as evidenced by the following,
    a. Appropriate use of air-locks and pressure cascade to confine potential airborne contaminant within a specified area were not effectively implemented (clause 5.21 (x) Technical Measures). For example, the pressure gauge reading for the wash bay on the mezzanine level of the Tableting/Dry Powder Suite indicated the pressure differential of the wash bay was positive to the central staging area of the mezzanine. This was not compliant with the facility design.
    b. On-going monitoring and preventative maintenance of the HVAC did not minimise the risks of contamination caused by recirculation or re-entry of untreated or insufficiently treated air (clause 5.21 (xi) Technical Measures). For example, confirmation of HEPA filter integrity in AHUs across the facility were limited to visual checks; however, this was not adequate to determine whether the HEPA filters had been perforated. HEPA filter integrity was a critical component of the sites HVAC design as the on-going monitoring program of room pressure differentials had no upper pressure limits, and AHUs had no pressure monitoring across their filter banks.

Response Date:

Date of completion:

Corrections:

Inspector's Review:

Response accepted?

Follow-up required at next inspection: Yes/No

TGA to complete		
Lead inspector sign off once all deficiencies are closed out	**Name:**	**Date:**

Australian Government
Department of Health
Therapeutic Goods Administration

s22
GMP Pharmaceuticals Pty Limited
60 Huntingwood Drive
Huntingwood
NSW 2148

Ref: PH23/20896

RE: **The *Therapeutic Goods Act 1989***
Surveillance inspection of GMP Pharmaceuticals Pty Limited
Inspection Tracking Number MI-2023-LI-03211-1

Dear s22

I would like to thank you and s22 for the courtesy and attention extended during the inspection conducted of GMP Pharmaceuticals Pty Limited on 3 – 4 April 2025.

During the inspection, a number of inspection findings, listed as deficiencies in the appendix to this letter, have been identified that indicate a departure from acceptable GMP standards, and these items require prompt resolution.

You are requested to respond to the deficiencies recorded below within four (4) weeks from the date of this letter. A standard form (in Word) to prepare the response has been issued with this letter. The preferable format for your response is:

- For the response form (Close out record): as a Word document that is not marked as final;
- For all deficiencies categorised as 'critical' or 'major' a CAPA plan should be submitted that includes root cause analysis, corrective action/s to the root cause, preventative action/s to the root cause, corrections to observed examples, and due date for completion of actions.
- For the deficiencies categorised as 'other', a CAPA plan is not required; however, the response date, the correction and due date for completion are required to be provided.

All correspondence regarding the inspection should be addressed to me at the email address below.

Yours sincerely

Signed and authorised by

s22
Senior Inspector
Manufacturing Quality Branch
Date: 11 April 2025

Phone: s22
E-mail: s22 @health.gov.au

APPENDIX

Scope of inspection

The inspection was conducted to review on-going compliance to the PIC/S Guide to GMP for Medicinal Products (PE-009-16) for operations at GMP Pharmaceuticals Pty Limited's Huntingwood facility via surveillance inspection, as per the following manufacturing table and licence conditions below:

Manufacturing Type	Sterility	Dosage Form	Product Code	Manufacturing Step
Medicine manufacture	Non Sterile	All Dosage Forms	Listed Therapeutic Good	Storage
Medicine manufacture	Non Sterile	All Dosage Forms	Listed Therapeutic Good	Testing
Medicine manufacture	Non Sterile	Powders Group	Listed Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Granules Group	Listed Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms - Tablets	Listed Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Capsule, hard	Listed Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Capsule, soft	Listed Therapeutic Good	Packaging, Labelling and Release for Supply

Condition: This licence does not authorise the manufacture of medicines listed for export that include substances at a level only permitted in medicines contained within schedules 2, 3, 4 & 8 of the Poisons Standard.

List of Deficiencies observed during the inspection

Critical deficiencies:

None observed

Major deficiencies:

1. The requirement of Clause 1.10 that regular periodic or rolling quality reviews of all authorised medicinal products, including export only products, should be conducted with the objective of verifying the consistency of the existing process, the appropriateness of current specifications for both starting materials and finished product, to highlight any trends and to identify product and process improvements; and these product quality reviews (PQRs) should normally be conducted and documented annually, were not fully met. For example, there were no formal processes in place to ensure PQRs were available for all authorised medicinal products manufactured at site, and to ensure PQRs were conducted annually (or every 2 years for low volume products). The inspector noted that the available PQRs may represent the full product range; however, GMP Pharmaceuticals approved process was to conduct individual, product based PQRs, rather than using a grouped product approach.

   A similar deficiency was recorded at the previous routine re-inspection conducted in May 2021.

2. The requirements of Clause 2.11 that newly recruited personnel should receive training appropriate to the duties assigned to them, continuing training should also be given, and its practical effectiveness should be periodically assessed, were not fully met. For example, processes for recording the effectiveness of on-the-job training had been formalised into procedures; however, the planned checklists for recording on-the-job training activities were still being developed and no records of on-the-job training were available.

A similar deficiency was recorded concerning on-the-job training at previous routine re-inspections, including that conducted in May 2021.

Other deficiencies:

3. The requirements of Annex 15 §10.9 that where campaign manufacture is carried out, the impact on the ease of cleaning at the end of the campaign should be considered and the maximum length of a campaign (in time and/or number of batches) should be the basis for cleaning validation exercises was not fully met. For example, cleaning validation protocols associated with the extension of campaign manufacturing activities, outlined in Quality Incident report, QID 24124, did not specify hard to clean locations on equipment, which could be impacted by the extended campaign length, to ensure these were reviewed for visual cleanliness and microbiological build-up.

4. The requirements of Annex 15 §11.4 concerning change control, that quality risk management should be used to evaluate planned changes to determine the potential impact on product quality, pharmaceutical quality systems, documentation, validation, regulatory status, calibration, maintenance and on any other system to avoid unintended consequences, and to plan for any necessary process validation, verification or requalification efforts, had not been fully implemented. For example, new product introduction processes did not consistently evaluate the need for process validation, nor formally evaluate whether the new product should be included in the site's on-going stability program. For example, regarding Change Control CC24163 for the transfer of Wonderland Capsules from GMP Pharmaceuticals Girraween site to the Huntingwood site,
    a. CC24163 did not identify process validation as a requirement, nor was there an evaluation recorded to ensure the new product was represented by the existing process validation product groups.
    b. CC24163 did not evaluate the need for an on-going stability study for the new product. It is acknowledged that on-going stability for this product was underway at the Girraween site; however, this was not documented in the change control and it was unclear whether manufacturing processes at the Huntingwood site would be comparable to those used at the Girraween site.

5. The requirements of clause 3.19 that storage areas should be designed or adapted to ensure good storage conditions, [. . .] they should be clean and dry and maintained within acceptable temperature limits, and where special storage conditions are required (e.g. temperature, humidity) these should be provided, checked and monitored, were not fully met. For example, the warehouse temperature in the locations used for storage of gelatine capsule shells were not specifically monitored. The warehouse temperatures were monitored at the 'worst case' locations and temperature excursions were only actioned when temperatures were above 30 °C. There was no evidence available to demonstrate the storage locations for gelatine capsule shells would remain at or below 25 °C, as required by the special storage conditions of the material. The temperature records indicated the 'worst case' locations were above 25 °C (and below 30 °C) on multiple occasions during January and February 2025.

6. The requirements of clause 5.19 that cross-contamination should be prevented by attention to design of the premises and equipment as described in Chapter 3 of the PIC/S Guide, and this should be supported by attention to process design and implementation of any relevant technical or organizational measures, including effective and reproducible cleaning processes to control risk of cross-contamination, were not fully met. For example, wash bays on both the mezzanine level and ground floors of the Tableting/Dry Powder Suite were noted to have black residue on some horizontal surfaces within the wet areas of the wash bay. The residue was present in/on sealant between wall panels and floor coving, and upon multiple horizontal ledges around the wash bay enclosures.

7. The requirements of clause 5.21 regarding technical measures required to control risks for cross-contamination were not fully met as evidenced by the following,
    a. Appropriate use of air-locks and pressure cascade to confine potential airborne contaminant within a specified area were not effectively implemented (clause 5.21 (x) Technical Measures). For example, the pressure gauge reading for the wash bay on the mezzanine level of the Tableting/Dry Powder Suite indicated the pressure differential of the wash bay was positive to the central staging area of the mezzanine. This was not compliant with the facility design.
    b. On-going monitoring and preventative maintenance of the HVAC did not minimise the risks of contamination caused by recirculation or re-entry of untreated or insufficiently treated air (clause 5.21 (xi) Technical Measures). For example, confirmation of HEPA filter integrity in AHUs across the facility were limited to visual checks; however, this was not adequate to determine whether the HEPA filters had been perforated. HEPA filter integrity was a critical component of the sites HVAC design as the on-going monitoring program of room pressure differentials had no upper pressure limits, and AHUs had no pressure monitoring across their filter banks.

DEFINITIONS

Marketing Authorisation

Compliance with regulatory requirements specified on the ARTG and any other requirements imposed by a relevant Delegate of Secretary upon product listing or registration.

Examples of regulatory requirements include but not limited to the following: compliance with registered formulations, special storage and transportation conditions, shelf life, labelling, batch release testing requirements etc.

Critical Deficiency

A deficiency in a practice or process that has produced, or may result in, a significant risk of producing a product that is harmful to the user. Also occurs when it is observed that the manufacturer has engaged in fraud, misrepresentation or falsification of products or data.

Major Deficiency

A non-critical deficiency that:

- has produced or may produce a product which does not comply with its marketing authorisation; and/or
- indicates a major deviation from the Code of GMP; and/or
- indicates a major deviation from the terms of the manufacturing licence or GMP approval (overseas manufacturers); and/or
- indicates a failure to carry out satisfactory procedures for release of batches; and/or
- indicates a failure of the person responsible for QA/QC to fulfil his/her duties; and/or
- consists of several other deficiencies, none of which on its own may be major, but which may together represent a major deficiency and should be explained and reported as such.

Other Deficiency

A deficiency that cannot be classified as either critical or major but indicates a departure from good manufacturing practice.

A deficiency may be "other" either because it is judged as minor, or because there is insufficient information to classify it as major or critical.

One-off minor lapses or less significant issues are usually not formally reported but are brought to the attention of the manufacturer.

Note:

1. Classification of a deficiency is based on the assessed risk level and may vary depending on the nature of products manufactured, e.g in some circumstances an example of major deficiency may be categorised as critical.
2. A deficiency that was reported at a previous inspection and not corrected may be reported in a higher classification.

Document 17

Australian Government
Department of Health
Therapeutic Goods Administration

Manufacturing Quality Branch

Inspection closing meeting summary

Manufacturer name:	GMP Pharmaceuticals Pty Limited
Manufacturer address:	60 Huntingwood Drive Huntingwood NSW 2148
Inspection type:	Surveillance re-inspection
Inspection date/s:	3 – 4 April 2025
Inspector/s:	s22
Inspection standard:	PIC/S Guide to Good Manufacturing Practice for Medicinal Products (PE009-16)

The following is a reflection of deficiencies against the requirements of the standard that were identified during the inspection. They may have also been discussed at a debrief meeting at the end of each day.

The deficiencies are not yet classified or referenced to the standard. Following further consideration and internal review, they may be reworded or grouped to accurately reference the applicable clause/s of the standard. The manufacturer is not required to respond to this interim document, but only to the list of deficiencies in the post inspection letter.

1. Cleaning validation protocols associated with the extension of the campaign manufacturing activities, outlined in Quality Incident report, QID 24124, did not specify or reference locations to be reviewed for visual cleanliness, which could be impacted by the extended campaign i.e., hard to clean after 14 days build-up of production residue.

2. New product introduction processes did not always formally document the need to conduct process validation, or commit the new product to the on-going stability program. For example, regarding Change Control CC24163 for the transfer of Wonderland Capsules from the Girraween site,
    a. The CC did not identify process validation as a requirement, nor was there a formal evaluation recorded to determine whether the new product was represented by the existing process validation product groups
    b. The CC did not identify a requirement to evaluate the need for an on-going stability study for the product. It is acknowledged that on-going stability for this product was underway at the Girraween site; however, it was unclear whether these studies would be analogous to the manufacturing processes used at the Huntingwood site.

3. The warehouse temperature in the locations used for storage of gelatine capsule shells were not specifically monitored. There was no evidence available to demonstrate these storage locations would remain at or below 25 °C, as required by the material. The current monitoring location/s for the warehouse temperatures were limited to the 'worst case' location determined by temperature mapping studies, which indicated some areas of the warehouse were above 25 °C during January and February.

4. Wash bays in the Tableting/Dry Powder Suite (both mezzanine and ground floor) were noted to have black residue on some horizontal surfaces within the wet areas of the wash bay e.g., sealant between wall panels and floor coving, horizontal ledges around the wash bay enclosure.

5. The pressure gauge reading for the wash bay on the mezzanine level of the Tableting/Dry Powder Suite pressure differential of the wash bay was positive to the central staging area

of the mezzanine. This was not compliant with the facility design. *It is noted that the issue was informally reported to the Engineering Department prior to the inspection; however, no actions obvious CAPA or risk mitigation strategies had been implemented at the time of inspection.*

6. The processes for recording on-the-job training had been outlined in procedures; however, the checklists for recording these activities were still being developed and no records of these activities were available.

7. There were no formal processes in place to ensure Periodic Product Reviews (PQRs) were available for each product manufactured at site, and to ensure PQR were conducted annually (or every 2 years for low volume products).

8. Confirmation of HEPA filter integrity was limited to visual checks; however, this would not determine whether the HEPA filters maintained their integrity. HEPA filter integrity was a key component of the current HVAC on-going monitoring program as room pressure differentials had no upper limit values, and AHUs had no pressure monitoring across the filter banks.

Updates from TGA since your previous inspection:

- The new Procedure for recalls, product alerts and product corrections (PRAC), took effect on 5 March 2025. The PRAC replaces the Uniform Recall Procedure for Therapeutic Goods (URPTG) as the procedure for sponsors to follow when conducting market actions in Australia.

Feedback & Complaints Process:

- The TGA's inspection of therapeutic goods manufacturers operates within a Quality Management System. We welcome feedback in relation to the conduct of inspections, and will ensure that TGA continuously improve our training and management systems. There are two types of feedback forms available. All relevant information, and both forms, can be found on the TGA website at: https://www.tga.gov.au/form/inspection-feedback-forms
    - The 'Inspection feedback form - routine' allows manufacturers to comment on the planning, conduct and communication of inspections. Manufacturers are encouraged to complete a form following each inspection and provide constructive feedback (both positive feedback and areas that need improvement).
    - The 'Inspection feedback form - interpretation of requirements' is also available. It is intended for use when a manufacturer has a different view concerning the interpretation of the Code of GMP, an international standard, or demonstrating compliance with an Essential Principle made by an inspector(s). Feedback received will be reviewed, assessed and used to monitor consistency of interpretation of manufacturing requirements.

  The feedback information will be used to improve inspection procedures and training given by the TGA.

Document 18

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Manufacturing
Quality
Branch

Surveillance Inspection Plan – Medicines & APIs

Manufacturer name:	GMP Pharmaceuticals Pty Limited
Manufacturer address:	60 Huntingwood Drive Huntingwood NSW 2148
Inspection type:	Surveillance re-inspection
Inspection dates:	3 – 4 April 2025
Inspectors:	s22
Inspection standard:	PIC/S Guide to Good Manufacturing Practice for Medicinal Products (PE009-16)

Time	Inspector	Activity/Element
Day 1:		
09.30-10.00		**Opening meeting** ❒ Introductions ❒ TGA updates ❒ Inspection Standard ❒ Inspection plan ❒ Review Application ❒ Buildings in scope of Inspection ❒ Company overview - description of manufacturing and product range ❒ Attendance record ❒ Inspection Process ❒ Inspection scope ❒ Breaks and use of facilities . ❒ Batch records
Pharmaceutical Quality System		
10.00-12.30		❒ Change control (3)(1) ❒ Complaints ❒ Supplier Evaluation (1) ❒ Product Quality Reviews (7 grouping + timeliness) ❒ Computerised systems (8) (6) ❒ Deviation & NCR (5), CAPA, OOS ❒ Recall activities ❒ Training (4)
12.30 – 13.15	**Lunch**	
Materials Control / Warehousing		
13.15 – 14.00		❒ Inventory Management System ❒ Raw Materials/Bulk Materials ❒ Rejects Control ❒ Retention/Reference Samples ❒ Temperature monitoring - warehouse mapping (2c) ❒ Status Control-Identification/Traceability ❒ Finished Goods ❒ Returned goods ❒ Cleaning/Housekeeping **Starting Materials** ❒ Sampling area/Plans ❒Control of pre-printed packaging
Production System		
14.00-16.00		**Dispensing Areas** ❒ Materials Flow **Production - Manufacture/Filling/labelling** ❒ Gowning/Access ❒ Contamination control – air/layout ❒ Mixing/Blending ❒ Batch record formats/entries ❒ Process flow ❒ Cleaning procedures/records ❒ Cleaning ❒ Water supply Room pressure monitoring systems (6) Coating machine failure alarms (7) **Dosage form specific equipment** ❒ Granules ❒ Powder ❒ Tablets (FC + disintegrating) ❒ Capsules

Time	Inspector	Activity/Element Document 18
16.00-17.00		**Batch Record Review and Batch Release** ❒ Line clearance ❒Traceability of materials ❒ Reconciliation ❒ Completeness/accuracy ❒ Environmental monitoring ❒ IPQC results ❒ Batch Release Process ❒ Marketing Auth./Regulatory compliance
17.00		**End Day 1**
Day 2:		
Facilities and Equipment		
8.30-9.30		❒ Calibration – dispensary scales (3) **HVAC** ❒ Area Classifications ❒ Pressures/Containment strategy ❒ Monitoring/Control/Testing/Trends ❒ Handling of alarms and trending ❒ Environmental Monitoring(6) (2) **Water Systems** ❒ Sanitisation ❒ Monitoring/Control/Testing/Trends Water (6 alerts & actions for OOS) (8 - weekly monitoring)
Validation/Qualification		
9.30-10.30		❒ VMP (2) ❒ Process validation for NPI ❒ Computerised systems ❒ Cleaning Validation (5 cleaning of chutes etc)
Quality Control		
10.30-12.00		**Chemistry** ❒ Specifications and test methods ❒ Reference standards ❒ Equipment calibration/maintenance ❒ Test results (raw data) ❒ System suitability ❒ OOS/OOT Procedures ❒ Test method validation 2f & 2g chem & micro ❒ Stability ❒ Instruments/Equipment ❒ Data Management
12.30 – 14.00	**Lunch & preparation for closing meeting**	
14.00-15.00		**Closing Meeting**
15.00		**Depart site**

The times indicated are for guidance only and can be modified to suit.

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Manufacturing
Quality
Branch

MQB - Form

FORM 5.2.a	Inspection Record		
Comes Under	SOP 5.2 – Inspection Preparation and Planning		
Process Owner	Director, Inspections	Authorised by	Quality Manager
Date Issued	7 June 2024	Version #	3.3

Section 1 – Inspection Preparation

Lead Inspector to complete this section when preparing to conduct an inspection, following SOP 5.2 – "Inspection Preparation and Planning".

Parameter:	Entry:
MIS Tracking Number:	MI-2023-LI-03211-1
Manufacturer Name:	GMP Pharmaceuticals Pty Limited
Date(s) of Inspection:	3 – 4 April 2025
Inspection Type(s):	☒Medicines ☐APIs ☐Bloods ☐Cellular Therapies ☐Tissues ☐Veterinary ☐Gene Therapies ☐Other (specify): ☐Re-inspection ☐Initial ☐Reduced scope ☒Surveillance ☐Special (select): ☐Close-out ☐Compliance
Inspection Method:	☒On-site ☐Remote ☐Hybrid
Sterility Status:	☒Non-sterile ☐Sterile

Inspection Scope: (SOP 5.2 Appendix 2)	Full product manufacture of non-sterile listed medicines in the form of tablets, hard capsules, powders and granules. Packaging, labelling & RFS of listed medicine soft gel capsules Storage of all non-sterile listed medicines dosage forms Testing of all non-sterile listed medicines dosage forms The inspection is a surveillance inspection with **reduced scope**, as detailed in the inspection plan (and outlined below in red)
2 items from each of the 5 streams	☐Stream 1 – Materials Control Warehousing ❒ GMP Contract agreements ❒ Control of storage areas ❒ Rejects Control ❒ Cleaning/Housekeeping ❒ Temperature/humidity monitoring ❒ Raw Materials/Bulk Materials ❒ Finished Goods ❒ Supplier Evaluation/API Audits ❒ Inventory Management System ❒ Returned goods ❒ Retention/Reference Samples ❒ Status Control-Identification/Traceability ❒ Waste Disposal ❒ Dispatch/Handling/Traceability Starting Materials ❒Receipt, Quarantine/Inspection/Testing ❒Control of utensils ❒Approval for use ❒Picking/Dispensing ❒Control of pre-printed packaging packaging/components ❒ Sampling area/Plans ❒ Retention Samples ❒ Cleaning/Housekeeping ❒ Control of Components ❒ Sampling/Approval of

☐ Stream 2 – Production System

Dispensing Areas

- ❒ Materials Flow
- ❒ Room grading
- ❒ Control of utensils
- ❒ Cleaning/Housekeeping
- ❒ Gowning/Access
- ❒ Equipment logs
- ❒ Retention Samples
- ❒ Containment

Production - Formulation Areas

- ❒ Materials Flow
- ❒ Room grading
- ❒ Water supply
- ❒ Preparation of solutions
- ❒ Solution Filtration
- ❒ IPQC testing
- ❒ Transfer of Bulk solutions to filling
- ❒ Gowning/Access
- ❒ Equipment logs
- ❒ Equipment CIP/SIP
- ❒ Mixing/Blending
- ❒ Bulk storage/monitoring
- ❒ Environmental Monitoring
- ❒ Batch record formats/entries

Production - Manufacture/Filling

- ❒ Process flow
- ❒ Batch record formats/entries
- ❒ Temp/Humidity/Pressure differentials
- ❒ Area condition/finishes
- ❒ Equipment CIP/SIP
- ❒ Dress codes/gowning/personal hygiene
- ❒ Cleaning procedures/records
- ❒ Contamination control – air/layout

- ❒ In-process checks/sampling
- ❒ Management of components

General

- ❒ Waste control
- ❒ Reconciliation
- ❒ Sampling plans (chem/micro)
- ❒ Line clearance
- ❒ Contamination control – air/layout

Production – Labelling/ Packaging

- ❒ Process flow
- ❒ Batch record formats/entries
- ❒ Temp/Humidity/Pressure differentials
- ❒ Area condition/finishes
- ❒ Labelling/Coding
- ❒ Reconciliation of components
- ❒ Check weighers/VISY
- ❒ Return of unused components
- ❒ Dress codes/gowning /personal hygiene
- ❒ Cleaning procedures/records
- ❒ Room grading
- ❒ Packaging Equipment
- ❒ IPQC checks & records
- ❒ Line clearance
- ❒ Rejected units
- ❒ Batch & Product displayed

IPC Laboratory

- ❒ Equipment calibrated/maintained
- ❒ Completion of Batch records
- ❒ Procedures/Records
- ❒ Cleaning procedures/records

☐ Stream 3 – Validation/ Qualification

- ❒ VMP (Schedule)
- ❒ Equipment List
- ❒ Document formats
- ❒ Equipment Qualification
- ❒ Revalidation

- ❒ Process validation and ongoing process verification
- ❒ Cleaning Validation/HBEL
- ❒ Computerised systems
- ❒ Temperature controlled areas

☐ Stream 4 – Facilities & Equipment

Review of Utilities & Services
- ❒ Preventive Maintenance
- ❒ Calibration
- ❒ Pest Control
- ❒ Waste Disposal

HVAC
- ❒ Area Classifications
- ❒ P&ID's
- ❒ Specifications/Design/Construction
- ❒ Filtration supply/return/exhaust
- ❒ Pressures/Containment strategy
- ❒ Room certification/airflow visualisation
- ❒ Monitoring/Control/Testing/Trends
- ❒ Handling of alarms and trending
- ❒ Operation/Checks/Cleaning
- ❒ Validation system/BMS/Alarms
- ❒ Power failure
- ❒ Equipment calibration and maintenance
- ❒ Environmental Monitoring

Water Systems
- ❒ Use / SOPs
- ❒ P&ID's
- ❒ Specifications/Design/Construction
- ❒ Sanitisation
- ❒ Monitoring/Control/Testing/Trends
- ❒ Operation/Checks/Cleaning
- ❒ Validation
- ❒ Equipment calibration and maintenance

Critical Production Equipment
- ❒ Use / SOPs
- ❒ P&ID's
- ❒ Specifications/Design/Construction
- ❒ Sterilisation/Sanitisation
- ❒ Monitoring/Control/Testing
- ❒ Operation/Checks/Cleaning
- ❒ Validation
- ❒ Equipment calibration and maintenance

Compressed air/gasses/vacuum (Natural Gas/O_2/N_2)
- ❒ Use / SOPs
- ❒ P&ID's
- ❒ Specifications/Design/Construction
- ❒ Sterilisation/Sanitisation
- ❒ Monitoring/Control/Testing
- ❒ Operation/Checks/Cleaning
- ❒ Validation
- ❒ Equipment calibration and maintenance

☐ Stream 5 – Quality Control

Chemistry
- ❒ Sample Preparation/Dispatch
- ❒ Stability
- ❒ Specifications and test methods
- ❒ Testing as per specification
- ❒ Test results (raw data)
- ❒ Method validation
- ❒ Reference standards
- ❒ Reagents/Volumetric Solutions
- ❒ Reference/retention samples
- ❒ Instruments/Equipment
- ❒ Equipment calibration/maintenance
- ❒ Equipment Qualification
- ❒ System suitability
- ❒ Water testing
- ❒ Personnel training
- ❒ Contract testing
- ❒ OOS/OOT Procedures
- ❒ Certificates of Analysis
- ❒ Release of results
- ❒ Data Management

Microbiology
- ❒ Sample Preparation/Dispatch
- ❒ Media Preparation/QC
- ❒ Culture collection
- ❒ Incubator monitoring/mapping
- ❒ Equipment Qualification
- ❒ Equipment calibration/maintenance
- ❒ Specifications
- ❒ Test methods
- ❒ Method validation
- ❒ Test results (raw data/computerised systems)
- ❒ OOS/OOT Procedures
- ❒ Water testing
- ❒ EM/PM (viable/non-viable)
- ❒ Antibiotic assays
- ❒ Data management
- ❒ Sample Preparation/Dispatch
- ❒ Contract testing
- ❒ Personnel training
- ❒ Certificates of Analysis
- ❒ Release of results

Initial email contact and email notification followed up with Inspection Announcement letter	Name s22 [redacted] Date: 11/3/2025 ☒Manufacturer ☐ Sponsor
Inspection preparation conducted and recorded/filed in accordance with SOP 5.2?	☒Yes ☐No (explain)
MIS pre-inspection task completed (WI 5.2.2)	☒Yes ☐No (explain)
~~International Biological manufacturer?~~	~~☐Yes ☐N/A~~ ~~Pre-inspection hours:~~

Section 2 – Inspection Conduct/Outcome

Lead Inspector to complete this section after conducting an inspection, following SOP 5.3 – "Conducting an Inspection".

Parameter:	Entry:		
Date back in office after Inspection:	7/04/2025		
Access denied?	☒No ☐Yes (explain)		
Sampling process (WI 5.3.7) conducted?	☐ Yes ☒ No	TRIM ref #	n/a
Any areas not covered during the inspection?	☒ No ☐ Yes (explain)		
Previous inspection findings: reviewed?	☐Yes, no further issues ☐ No (explain)	☒Yes, repeat issues identified ☐N/A	
Recalls verified on site? (Form 5.1.1a):	☐Yes, no further issues ☐ No (explain)	☐Yes, issues identified ☒N/A	
Inspection conducted and recorded/filed in accordance with SOP 5.3/5.4:	☒ Yes ☐ No (explain)		
Conflict of interest: Financial or other interest in inspected company?	☒ No ☐ Yes (explain)	Were gift / meal / other hospitality / travel / entertainment, etc. provided?	☒ No ☐ Yes (explain)

Inspection outcome			
Provisional compliance rating	☐ 1st A1 rating ☐ 2nd consecutive repeat ☐ 3rd or subsequent repeat		
	☒ A2		
	☐ A3 ☐ Repeat A3		
	☐ Unacceptable		
Referred to Review Panel (SOP 5.5)	☒ No ☐ Yes	Date referred: TRIM review panel folder ref #	n/a
MIS [Audit Document] data completed (WI 5.3.8)?	☒ Yes ☐ No (explain)		
Date PIL submitted for review (WI 5.3.10):	11/04/2025		
LI comments:	☒ N/A		

Reinspection Details	
Risk Category:	☐ High ☐ Medium ☐ Low ☒ Listed
Months to next inspection:	~~(H/M/L) ☐ 12 ☐ 15 ☐ 18 ☐ 20 ☐ 24 ☐ 36~~ (Listed) ☐ 18 ☒ 30 ☐ 42 ☐ 48 Comment:
LI recommended next inspection:	Team composition: 1 inspector Duration: 4 days Reaudit raised by LI as above ~~Reduced scope inspection: ☐ Yes ☐ No If yes, what is recommended.~~ ~~For medicines:~~ ~~☐ Stream 1 Materials Control ☐ Stream 2 Production System ☐ Stream 3 Validation/ Qualification ☐ Stream 4 Facilities & Equipment ☐ Stream 5 Quality Control~~
Inspection Notes	
Record any notes relevant to the inspection that may be useful to subsequent inspections, e.g. site access, travel/transport, accommodation, isolated work, PPE/WHS concerns, language barriers, alerts etc.	☒ N/A

Section 3 – PIL Peer Review / Create re-inspection

Peer reviewer to complete this section after reviewing the PIL for compliance with WI 5.3.10 "Writing a Post-inspection Letter (PIL)" and creating a re-inspection following SOP WI 5.3.11 "Creating a re-audit in MIS".

Parameter:	Entry:
Reviewer name:	s22 [redacted]
All requirements of WI 5.3.10 met?	☒ Yes ☐ No (explain)
Any feedback on PIL to LI required?	☒ No ☐ Yes (explain)
Need to see the PIL again?	☒ No ☐ Yes (explain)
Provisional compliance rating:	☒ Agree ☐ Disagree (explain)
If disagree then changed to:	☐ N/A
Refer to Review Panel?	☒ No ☐ Yes (explain)
Reinspection raised (MIS) (WI 5.3.11):	☒ Yes ☐ No (explain) **Raised by** s 2 [redacted]
Reviewer's comments:	☐ N/A Good PIL
Lead Inspector to complete MIS Audit [Inspection] task following PIL review (WI 5.3.8):	☒ Yes ☐ No (explain)

Section 4 – Inspection Close-out & Report

Parameter:	Entry:		
Date PIL sent to manufacturer:	**11/04/2025**		
Date APVMA report sent: (for inspections performed under the MRA provisions)	☒N/A		
Date close-out report sent to manufacturer (WI 5.4.7):	**30/5/2025**		
Inspection close-out conducted and recorded/filed in accordance with SOP 5.4 & WI 5.4.6:	☒ Yes ☐ No (explain)		
~~International Biological manufacturer?~~	~~☐Yes ☐N/A~~ ~~Post inspection hours:~~		
	~~Date:~~	~~Hours:~~	
Final compliance rating:	☒As provisional ☐changed to AX If rating was changed – confirm reinspection details changed Explanation:		
Based on manufacturers response, is the duration of the next inspection sufficient? (WI 5.4.6)	☒ Yes ☐ No (explain if any additional time added) ~~**Additional time added:**~~ ~~MIS re-inspection amended: ☐ Yes~~		
Licence/certification/ clearance processing initiated:	☐ Yes ☒ No (explain)		
MIS POST Audit [Inspection] task completed (WI 5.4.3):	☐ No ☒ Yes (explain)		
Peer notified to complete Audit Completion task in MIS (WI 5.4.4)	☒ Yes ☐ No	Name of peer notified:	s22 [redacted]
e-signed (PIL, REPORT, THIS FORM) in TRIM:	☒ Yes ☐ No		

From: s22 [redacted]
To:
Cc:
Subject: TGA Inspection Report - GMP Pharmaceuticals - Huntingwood - April 2025 [SEC=OFFICIAL]
Date: Friday, 30 May 2025 10:41:30 AM
Attachments: image008.png
image009.png
image010.png
image011.png
image012.png
image013.png
image014.png
image015.jpg
image016.png
image017.png
image018.png
image019.gif
image020.png
TGA Surveillance Inspection Report - GMP Pharmaceuticals - Huntingwood - April 2025.pdf

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Dear s22 [redacted]

Please find attached the final inspection report, which also signifies the official close-out notification for your recent TGA inspection. The inspection process is now finalised.

Kind regards,
s22 [redacted]

s22 [redacted] (She/They)
Senior Inspector

Inspections and Compliance | Manufacturing Quality Branch
Australian Government, Department of Health, Disability and Ageing
Therapeutic Goods Administration

Location: Remote
s22 [redacted]@health.gov.au

This email comes to you from Awabakal Country
PO Box 100, Woden ACT 2606
www.tga.gov.au

The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 [redacted]@gmp.com.au>
Sent: Tuesday, 6 May 2025 4:59 PM
To: s22 [redacted]@health.gov.au>
Cc: s22 [redacted]@gmp.com.au>
Subject: Re: TGA Post Inspection Letter - GMP Pharmaceuticals - Huntingwood - April 2025 [SEC=OFFICIAL]

Hi s22 [redacted],

Thank you.

s22 | **QA Manager**

P: s22 | **M**: +s22
E: s22 @gmp.com.au | www.gmp.com.au

14 Amax Avenue, GIRRAWEEN
New South Wales 2145
Australia

60 Huntingwood Drive, HUNTINGWOOD
New South Wales 2148
Australia

Global Headquarters
60 Huntingwood Drive, Huntingwood NSW 2148

From: s22 @health.gov.au>
Sent: 06 May 2025 16:49
To: s22 @gmp.com.au>
Cc: s22 @gmp.com.au>
Subject: RE: TGA Post Inspection Letter - GMP Pharmaceuticals - Huntingwood - April 2025 [SEC=OFFICIAL]

Dear s22

I have reviewed and accepted each of the responses provided for the deficiencies recorded at the recent TGA inspection of GMP Pharmaceuticals Huntingwood facility. I have attached a copy of the reviewed close-out document for your records.

No further information is required, and the inspection is now finalised. I will prepare the final inspection report and have it issued to you in the next week or two.

Thank you and the GMP Pharmaceuticals team for all your support throughout the inspection process.

Kind regards
s22

s22 (she/they)
Senior Inspector
Inspections and Compliance | Manufacturing Quality Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s22 @health.gov.au
Location: Remote
Post: PO Box 100, Woden ACT 2606 Australia
www.tga.gov.au

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This is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met

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From: s22 @gmp.com.au>
Sent: Monday, 5 May 2025 3:35 PM
To: s22 @health.gov.au>
Cc: s22 @gmp.com.au>
Subject: Re: TGA Post Inspection Letter - GMP Pharmaceuticals - Huntingwood - April 2025 [SEC=OFFICIAL]

Hi s22 ,

Please find the filled close-out report. Please feel free to contact me if you have any question. Thank you.

s22 | QA Manager

P: s22 | M: s22
E: s22 @gmp.com.au | www.gmp.com.au

14 Amax Avenue, GIRRAWEEN New South Wales 2145 Australia

60 Huntingwood Drive, HUNTINGWOOD New South Wales 2148 Australia

Global Headquarters
60 Huntingwood Drive, Huntingwood NSW 2148

From: s22 [redacted] @health.gov.au>
Sent: 11 April 2025 14:28
To: s22 [redacted] @gmp.com.au>
Cc: s22 [redacted] @gmp.com.au>
Subject: TGA Post Inspection Letter - GMP Pharmaceuticals - Huntingwood - April 2025 [SEC=OFFICIAL]

Dear s22 [redacted]

Please find attached the Post Inspection Letter (PIL) for the surveillance re-inspection that took place at GMP Pharmaceuticals Huntingwood premises on 3 – 4 April 2025.

I have also included a pre-populated Close Out Record, which you can use to record your responses.

As discussed at the closing meeting, you are requested to provide a description of your proposed corrective actions and a timeframe for completion if unable to complete them prior to responding to me. Objective evidence is **not** required for the deficiencies identified.

You are requested to provide your response to me by **9 May 2025**.

Thank you again for your assistance and hospitality throughout the inspection. I look forward to reviewing your response once it becomes available in the next month or so. Please do not hesitate to contact me should you need clarification regarding the inspection or the PIL.

Could you please send me a brief email as soon as you receive this message to let me know the attachments arrived to you.

Regards
s22 [redacted]

s22 [redacted] (she/they)
Senior Inspector

Inspections and Compliance | Manufacturing Quality Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s22 @health.gov.au
Location: Remote
Post: PO Box 100, Woden ACT 2606 Australia
www.tga.gov.au

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From: s22
Sent: Friday, 4 April 2025 1:55 PM
To: s22 gmp.com.au>
Cc: s22 @gmp.com.au>
Subject: TGA Inspection closing meeting summary - GMP Pharmaceuticals - Huntingwood - April 2025 [SEC=OFFICIAL]

Dear s22

Please find attached the closing meeting summary for the inspection.

Regards
s22

s22 (she/they)
Senior Inspector
Inspections and Compliance | Manufacturing Quality Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s22 @health.gov.au
Location: Remote
Post: PO Box 100, Woden ACT 2606 Australia
www.tga.gov.au

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From: s22 @gmp.com.au>
Sent: Wednesday, 2 April 2025 3:12 PM

To: s22 @health.gov.au>
Cc: s22 @gmp.com.au>
Subject: Re: Inspection plan for Huntingwood TGA Audit [SEC=OFFICIAL]

Hi s22

Well received. Thank you. See you tomorrow.

s22 | **QA Manager**

P: s22 | s22
E: s22 @gmp.com.au | www.gmp.com.au

14 Amax Avenue, GIRRAWEEN
New South Wales 2145
Australia

60 Huntingwood Drive, HUNTINGWOOD
New South Wales 2148
Australia

Global Headquarters
60 Huntingwood Drive, Huntingwood NSW 2148

From: s22 @health.gov.au>
Sent: 02 April 2025 14:53
To: s22 @gmp.com.au>
Cc: s22 @gmp.com.au>
Subject: Inspection plan for Huntingwood TGA Audit [SEC=OFFICIAL]

Dear s22

My apologies for attaching the incorrect version of the plan to my previous email.

Please use the one attached here for this week's inspection.

Regards
s22

s22 (she/they)
Senior Inspector
Inspections and Compliance | Manufacturing Quality Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s22 @health.gov.au
Location: Remote
Post: PO Box 100, Woden ACT 2606 Australia
www.tga.gov.au

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From: s22
Sent: Wednesday, 2 April 2025 2:48 PM
To: s22 @gmp.com.au>
Cc: s22 @gmp.com.au>
Subject: RE: Required Documents for Huntingwood TGA Audit [SEC=OFFICIAL]

Dear s22 ,

Please find attached the plan for this week's inspection. We can discuss the plan during the opening meeting and adjust as required by staff availability.

I will be at the Huntingwood site by 9.30 AM tomorrow.

Regards
s22

s22 (she/they)
Senior Inspector
Inspections and Compliance | Manufacturing Quality Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s22 @health.gov.au
Location: Remote
Post: PO Box 100, Woden ACT 2606 Australia
www.tga.gov.au

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From: s22
Sent: Tuesday, 25 March 2025 2:20 PM
To: s22 @gmp.com.au>
Cc: s22 @gmp.com.au>
Subject: RE: Required Documents for Huntingwood TGA Audit [SEC=OFFICIAL]

Dear s22

Thank you providing the requested documents. All are well received.

Regards
s22

s22 (she/they)
Senior Inspector
Inspections and Compliance | Manufacturing Quality Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s22
Location: Remote
Post: PO Box 100, Woden ACT 2606 Australia
www.tga.gov.au

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This is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met

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From: s22 @gmp.com.au>
Sent: Monday, 24 March 2025 5:10 PM
To: s22 @health.gov.au>
Cc: s22 @gmp.com.au>
Subject: Required Documents for Huntingwood TGA Audit

Hi s22

Please find required documents for Huntingwood site audit.
Our production manager, Pradip, just left GMP the week before last week, so our site master file did not capture the change. Related change control is attached.
Please feel free to contact me if you have any question. Thank you.

s22 | QA Manager

P: s22

E: s22 @gmp.com.au | www.gmp.com.au

14 Amax Avenue, Drive, GIRRAWEEN New South Wales 2145 Australia

60 Huntingwood HUNTINGWOOD New South Wales 2148 Australia

Global Headquarters
60 Huntingwood Drive, Huntingwood NSW 2148

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

s22
Quality Manager
GMP Pharmaceuticals Pty Limited
60 Huntingwood Drive
Huntingwood
NSW 2148

Our Reference: PH23/20896

Dear s22

Subject: GMP Surveillance Inspection of GMP Pharmaceuticals Pty Limited

Please find attached the inspection report for the surveillance inspection that took place at GMP Pharmaceuticals Pty Limited's Huntingwood facility on 3 – 4 April 2025.

Your response(s) to the deficiencies reported in the post inspection letter have been evaluated and have been accepted. Effective implementation will be reviewed at the next GMP inspection.

You should note that assessments made during Surveillance Inspections are based on a random and limited examination and verification of the manufacturer's documents. This inspection report does not therefore claim to be a complete evaluation of all manufacturing operations performed at your site, and does not release you from the obligation to rectify deficiencies that have not been identified or stated herein.

Should you have any questions regarding the inspection, please do not hesitate to contact me.

Yours sincerely

Signed and authorised by

s22
Senior GMP Inspector
Manufacturing Quality Branch

Date: 30 May 2025
Tel: s22
E-mail: s22 @health.gov.au

Surveillance Inspection Report

Manufacturer:	GMP Pharmaceuticals Pty Limited
Inspected site/s:	60 Huntingwood Drive, Huntingwood NSW 2148
Manufacturer information:	GMP Pharmaceuticals Pty Ltd (GMPP) is a manufacturer of listed therapeutic goods. GMPP holds 3 TGA licences to manufacture listed therapeutic goods. All licenced sites are located in western Sydney, in the suburbs of Girraween and Huntingwood. The facilities have been commissioned for the manufacture of both food and listed therapeutic goods. The Huntingwood site is in a light industrial area approximately 7 kilometres west of the Girraween complex and has held a TGA licence since 2020. The Huntingwood site continues to expand its portfolio of medicinal products, primarily with additional solid unit dosage form products. The manufacture food products was excluded from the scope of this insepction.
Activities carried out by manufacturer:	☑ Manufacture of finished medicinal product ☐ Manufacture of intermediate or bulk ☐ Packaging ☐ Laboratory testing ☐ Release for supply ☐ Manufacture of Active Pharmaceutical Ingredient ☐ Other:
Type of inspection:	☑ Re-inspection ☑ Surveillance inspection ☐ Remote inspection ☐ Hybrid inspection Applicable sections of the *Therapeutic Goods Act 1989*: ☑ section 40(4)(b) (re-inspection of licensed site) ☐ section 25(1)(g) (overseas in relation to registration) ☐ sections 26(1)(g), 26A(3) (overseas in relation to listing)
Scope of Inspection	Finished product manufacture of listed medicine in powder, granule, tablet and hard shell capsule dosage forms. Packaging, labelling and release for supply of listed medicine in soft gel capsule dosage form. Storage and testing of listed medicine in all dosage forms.
Inspection date/s:	3 – 4 April 2025
Inspector:	s22 [redacted]

Manufacturing Standard used:	PIC/S Guide to Good Manufacturing Practice for Medicinal Products, Part I (PE 009-16)
References:	Manufacturing Licence number: MI-2019-LI-01002-1 Inspection tracking number: MI-2023-LI-03211-1 File reference number/s: PH22/23917 (inspection file), E19-540033 (licence file)

Personnel met during the inspection

s22 QA Manager
s22 Quality & Compliance Manager

Inspected areas, findings and observations

Refer to Site Master File, SMF001 version 8, effective December 2025, for information of site activities.

Major changes since the previous inspection:

- Multiple new products introduced to site
- Changes to key personnel at Huntington; replaced by suitably experienced staff from GMP Pharmaceuticals' Girraween complex
- Upgrade or replacement to some ancillary production and laboratory equipment

Future Planned Changes: None discussed

Quality Management	
Subject area inspected	**Compliance outcome / comments**
Review of actions taken since previous inspection	Deficiencies 1 & 2 recorded at this inspection were similar to deficiencies recorded at the previous routine re-inspections of May 2021.
Product Quality Reviews	Refer to deficiency 1. A similar deficiency was recorded at the previous routine re-inspection conducted in May 2021.
Change Management	Refer to deficiency 4
Complaints management	No deficiencies identified
Deviation, non-conformance and CAPA management	No deficiencies identified
Internal Audits	No deficiencies identified
Batch Record Review and Batch Release	No deficiencies identified
Training	Refer to deficiency 2. A similar deficiency was recorded concerning on-the-job training at previous routine re-inspections, including that conducted in May 2021.

Materials Management	
Subject area inspected	**Compliance outcome / comments**
Warehousing	Refer to deficiency 5
Starting Materials	No deficiencies identified
Production System	
Subject area inspected	**Compliance outcome / comments**
Production - Formulation Areas	Refer to deficiency 6
Production - Manufacture/Filling	No deficiencies identified
Production – Labelling/ Packaging	No deficiencies identified
Validation/Qualification	
Subject area inspected	**Compliance outcome / comments**
Process Validation	Refer to deficiency 4a
Cleaning Validation	Refer to deficiency 3
Computer System Validation	No deficiencies identified
Facilities and Equipment	
Subject area inspected	**Compliance outcome / comments**
HVAC	Refer to deficiency 7
Water Systems	No deficiencies identified
Quality Control	
Subject area inspected	**Compliance outcome / comments**
Chemistry Laboratory	No deficiencies identified
Control of OOS results	No deficiencies identified

List of Deficiencies observed during the inspection

Critical deficiencies:

None observed

Major deficiencies:

1. The requirement of Clause 1.10 that regular periodic or rolling quality reviews of all authorised medicinal products, including export only products, should be conducted with the objective of verifying the consistency of the existing process, the appropriateness of current specifications for both starting materials and finished product, to highlight any trends and to identify product and process improvements; and these product quality reviews (PQRs) should normally be conducted and documented annually, were not fully met. For example, there were no formal processes in place to ensure PQRs were available for all authorised medicinal products manufactured at site, and to ensure PQRs were conducted annually (or every 2 years for low volume products). The inspector noted that the available PQRs may represent the full product range; however, GMP Pharmaceuticals approved process was to conduct individual, product based PQRs, rather than using a grouped product approach.

2. The requirements of Clause 2.11 that newly recruited personnel should receive training appropriate to the duties assigned to them, continuing training should also be given, and its practical effectiveness should be periodically assessed, were not fully met. For example, processes for recording the effectiveness of on-the-job training had been formalised into procedures; however, the planned checklists for recording on-the-job training activities were still being developed and no records of on-the-job training were available.

Other deficiencies:

3. The requirements of Annex 15 §10.9 that where campaign manufacture is carried out, the impact on the ease of cleaning at the end of the campaign should be considered and the maximum length of a campaign (in time and/or number of batches) should be the basis for cleaning validation exercises was not fully met. For example, cleaning validation protocols associated with the extension of campaign manufacturing activities, outlined in Quality Incident report, QID 24124, did not specify hard to clean locations on equipment, which could be impacted by the extended campaign length, to ensure these were reviewed for visual cleanliness and microbiological build-up.

4. The requirements of Annex 15 §11.4 concerning change control, that quality risk management should be used to evaluate planned changes to determine the potential impact on product quality, pharmaceutical quality systems, documentation, validation, regulatory status, calibration, maintenance and on any other system to avoid unintended consequences, and to plan for any necessary process validation, verification or requalification efforts, had not been fully implemented. For example, new product introduction processes did not consistently evaluate the need for process validation, nor formally evaluate whether the new product should be included in the site's on-going stability program. For example, regarding Change Control CC24163 for the transfer of Wonderland Capsules from GMP Pharmaceuticals Girraween site to the Huntingwood site,
    a. CC24163 did not identify process validation as a requirement, nor was there an evaluation recorded to ensure the new product was represented by the existing process validation product groups.
    b. CC24163 did not evaluate the need for an on-going stability study for the new product. It is acknowledged that on-going stability for this product was underway at the Girraween site; however, this was not documented in the change control and it was unclear whether manufacturing processes at the Huntingwood site would be comparable to those used at the Girraween site.

5. The requirements of clause 3.19 that storage areas should be designed or adapted to ensure good storage conditions, [. . .] they should be clean and dry and maintained within acceptable temperature limits, and where special storage conditions are required (e.g. temperature, humidity) these should be provided, checked and monitored, were not fully met. For example, the warehouse temperature in the locations used for storage of gelatine capsule shells were not specifically monitored. The warehouse temperatures were monitored at the 'worst case' locations and temperature excursions were only actioned when temperatures were above 30 °C. There was no evidence available to demonstrate the storage locations for gelatine capsule shells would remain at or below 25 °C, as required by the special storage conditions of the material. The temperature records indicated the 'worst case' locations were above 25 °C (and below 30 °C) on multiple occasions during January and February 2025.

6. The requirements of clause 5.19 that cross-contamination should be prevented by attention to design of the premises and equipment as described in Chapter 3 of the PIC/S Guide, and this should be supported by attention to process design and implementation of any relevant technical or organizational measures, including effective and reproducible cleaning processes to control risk of cross-contamination, were not fully met. For example, wash bays on both the mezzanine level and ground floors of the Tableting/Dry Powder Suite were noted to have black residue on some horizontal surfaces within the wet areas of the wash bay. The residue was present in/on sealant between wall panels and floor coving, and upon multiple horizontal ledges around the wash bay enclosures.

7. The requirements of clause 5.21 regarding technical measures required to control risks for cross-contamination were not fully met as evidenced by the following,
    a. Appropriate use of air-locks and pressure cascade to confine potential airborne contaminant within a specified area were not effectively implemented (clause 5.21 (x) Technical Measures). For example, the pressure gauge reading for the wash bay on the mezzanine level of the Tableting/Dry Powder Suite indicated the pressure differential of the wash bay was positive to the central staging area of the mezzanine. This was not compliant with the facility design.
    b. On-going monitoring and preventative maintenance of the HVAC did not minimise the risks of contamination caused by recirculation or re-entry of untreated or insufficiently treated air (clause 5.21 (xi) Technical Measures). For example, confirmation of HEPA filter integrity in AHUs across the facility were limited to visual checks; however, this was not adequate to determine whether the HEPA filters had been perforated. HEPA filter integrity was a critical component of the sites HVAC design as the on-going monitoring program of room pressure differentials had no upper pressure limits, and AHUs had no pressure monitoring across their filter banks.

Comments
None

Summary and conclusions

Assessment of manufacturer's responses
A response to the deficiencies reported to the manufacturer was received on 5 May 2025. The manufacturer's corrective actions have been evaluated and accepted, based on the agreement that all corrective actions will be carried out as described in the inspection close out correspondence.

Final evaluation and recommendations:
1. The manufacturer operates in accordance with the relevant GMP requirements.

2. TGA records have been updated to show a final compliance rating of your facility of A2: satisfactory compliance with the manufacturing standard established under the *Therapeutic Goods Act 1989*.

3. The next re inspection is expected to be performed within 30 months.

4. The duration of the next inspection is estimated at this time to be 4 days and will be conducted as a Full Inspection.

Signed and authorised by

s22
Senior Inspector
Manufacturing Quality Branch

Date: 30 May 2025
Mobile: s22
E-mail: s22 @health.gov.au

From: s22
To:
Cc:
Subject: RE: TGA Post Inspection Letter - GMP Pharmaceuticals - Huntingwood - April 2025 [SEC=OFFICIAL]
Date: Tuesday, 6 May 2025 4:49:34 PM
Attachments: image001.png
image002.png
image003.png
image004.gif
image005.png
image006.png
image007.jpg
TGA Close Out Record - GMP Pharmaceuticals - Huntingwood - Response reviewed & accepted by TGA.pdf

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Dear s22

I have reviewed and accepted each of the responses provided for the deficiencies recorded at the recent TGA inspection of GMP Pharmaceuticals Huntingwood facility. I have attached a copy of the reviewed close-out document for your records.

No further information is required, and the inspection is now finalised. I will prepare the final inspection report and have it issued to you in the next week or two.

Thank you and the GMP Pharmaceuticals team for all your support throughout the inspection process.

Kind regards
s22

s22 (she/they)
Senior Inspector
Inspections and Compliance | Manufacturing Quality Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s22 @health.gov.au
Location: Remote
Post: PO Box 100, Woden ACT 2606 Australia
www.tga.gov.au

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met

---

From: s22 @gmp.com.au>
Sent: Monday, 5 May 2025 3:35 PM
To: s22 @health.gov.au>
Cc: s22 @gmp.com.au>
Subject: Re: TGA Post Inspection Letter - GMP Pharmaceuticals - Huntingwood - April 2025 [SEC=OFFICIAL]

Hi s22

Please find the filled close-out report. Please feel free to contact me if you have any question. Thank you.

s22 | **QA Manager**

P: s22 | **M**: s22
E: s22 @gmp.com.au | www.gmp.com.au

14 Amax Avenue, GIRRAWEEN
New South Wales 2145
Australia

60 Huntingwood Drive, HUNTINGWOOD
New South Wales 2148
Australia

Global Headquarters
60 Huntingwood Drive, Huntingwood NSW 2148

From: s22 @health.gov.au>
Sent: 11 April 2025 14:28
To: s22 @gmp.com.au>
Cc: s22 @gmp.com.au>
Subject: TGA Post Inspection Letter - GMP Pharmaceuticals - Huntingwood - April 2025 [SEC=OFFICIAL]

Dear s22,

Please find attached the Post Inspection Letter (PIL) for the surveillance re-inspection that took place at GMP Pharmaceuticals Huntingwood premises on 3 – 4 April 2025.

I have also included a pre-populated Close Out Record, which you can use to record your responses.

As discussed at the closing meeting, you are requested to provide a description of your proposed

corrective actions and a timeframe for completion if unable to complete them prior to responding to me. Objective evidence is **not** required for the deficiencies identified.

You are requested to provide your response to me by **9 May 2025**.

Thank you again for your assistance and hospitality throughout the inspection. I look forward to reviewing your response once it becomes available in the next month or so. Please do not hesitate to contact me should you need clarification regarding the inspection or the PIL.

Could you please send me a brief email as soon as you receive this message to let me know the attachments arrived to you.

Regards
s22

s22 (she/they)
Senior Inspector
Inspections and Compliance | Manufacturing Quality Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
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---

From: s22
Sent: Friday, 4 April 2025 1:55 PM
To: s22 @gmp.com.au>
Cc: s22 @gmp.com.au>
Subject: TGA Inspection closing meeting summary - GMP Pharmaceuticals - Huntingwood - April 2025 [SEC=OFFICIAL]

Dear s22

Please find attached the closing meeting summary for the inspection.

Regards
s22

s22 (she/they)
Senior Inspector

Inspections and Compliance | Manufacturing Quality Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s22 @health.gov.au
Location: Remote
Post: PO Box 100, Woden ACT 2606 Australia
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---

From: s22 @gmp.com.au>
Sent: Wednesday, 2 April 2025 3:12 PM
To: s22 @health.gov.au>
Cc: s22 @gmp.com.au>
Subject: Re: Inspection plan for Huntingwood TGA Audit [SEC=OFFICIAL]

Hi s22

Well received. Thank you. See you tomorrow.

s22 | QA Manager

P: s22 | M: s22
E: s22 @gmp.com.au | www.gmp.com.au

14 Amax Avenue, GIRRAWEEN
New South Wales 2145
Australia

60 Huntingwood Drive, HUNTINGWOOD
New South Wales 2148
Australia

Global Headquarters
60 Huntingwood Drive, Huntingwood NSW 2148

From: s22 @health.gov.au>
Sent: 02 April 2025 14:53
To: s22 @gmp.com.au>
Cc: s22 @gmp.com.au>
Subject: Inspection plan for Huntingwood TGA Audit [SEC=OFFICIAL]

Dear s22

My apologies for attaching the incorrect version of the plan to my previous email.

Please use the one attached here for this week's inspection.

Regards
s22

s22 (she/they)
Senior Inspector
Inspections and Compliance | Manufacturing Quality Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s22 @health.gov.au
Location: Remote
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---

From: s22
Sent: Wednesday, 2 April 2025 2:48 PM
To: s22 @gmp.com.au>
Cc: s22 @gmp.com.au>
Subject: RE: Required Documents for Huntingwood TGA Audit [SEC=OFFICIAL]

Dear s22

Please find attached the plan for this week's inspection. We can discuss the plan during the opening meeting and adjust as required by staff availability.

I will be at the Huntingwood site by 9.30 AM tomorrow.

Regards
s22

s22 (she/they)
Senior Inspector
Inspections and Compliance | Manufacturing Quality Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s22 @health.gov.au
Location: Remote
Post: PO Box 100, Woden ACT 2606 Australia
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---

From: s22
Sent: Tuesday, 25 March 2025 2:20 PM
To: s22 @gmp.com.au>
Cc: s22 @gmp.com.au>
Subject: RE: Required Documents for Huntingwood TGA Audit [SEC=OFFICIAL]

Dear s22

Thank you providing the requested documents. All are well received.

Regards
s22

s22 (she/they)
Senior Inspector
Inspections and Compliance | Manufacturing Quality Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s22 @health.gov.au
Location: Remote
Post: PO Box 100, Woden ACT 2606 Australia
www.tga.gov.au

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cultures, and to all Elders both past and present.

This is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met

---

From: s22 [redacted] @gmp.com.au>
Sent: Monday, 24 March 2025 5:10 PM
To: s22 [redacted] @health.gov.au>
Cc: s22 [redacted] ohn@gmp.com.au>
Subject: Required Documents for Huntingwood TGA Audit

Hi s22 [redacted],

Please find required documents for Huntingwood site audit.
Our production manager, s22 [redacted], just left GMP the week before last week, so our site master file did not capture the change. Related change control is attached.
Please feel free to contact me if you have any question. Thank you.

s22 [redacted] | **QA Manager**

s22 [redacted]

E: s22 [redacted] gmp.com.au |
www.gmp.com.au

14 Amax Avenue, Drive,
GIRRAWEEN
New South Wales 2145
Australia

60 Huntingwood
HUNTINGWOOD
New South Wales 2148
Australia

Global Headquarters
60 Huntingwood Drive, Huntingwood NSW 2148

Close Out Record

Manufacturer name:	GMP Pharmaceuticals Pty Limited
Manufacturer address:	60 Huntingwood Drive Huntingwood NSW 2148
Inspection type:	Surveillance re-inspection
Inspection date/s:	3 – 4 April 2025
Inspector/s:	s22 [redacted]
Inspection standard:	PIC/S Guide to Good Manufacturing Practice for Medicinal Products (PE009-16)

Major Deficiencies

Please Note: CAPA plan required as evidence for major deficiencies that includes root cause analysis, corrective action/s to the root cause, preventative action/s to the root cause, corrections to observed examples, and due date for completion of actions. See headings below to be used for the response

Major Deficiency:

1. The requirement of Clause 1.10 that regular periodic or rolling quality reviews of all authorised medicinal products, including export only products, should be conducted with the objective of verifying the consistency of the existing process, the appropriateness of current specifications for both starting materials and finished product, to highlight any trends and to identify product and process improvements; and these product quality reviews (PQRs) should normally be conducted and documented annually, were not fully met. For example, there were no formal processes in place to ensure PQRs were available for all authorised medicinal products manufactured at site, and to ensure PQRs were conducted annually (or every 2 years for low volume products). The inspector noted that the available PQRs may represent the full product range; however, GMP Pharmaceuticals approved process was to conduct individual, product based PQRs, rather than using a grouped product approach.

Response Date: 30/04/2025

Date of completion: 31/05/2025

Identified Root Cause: Currently we are using Product-specific pathway for doing PQR. There is no certain month decided for reviewing all the products. Products that only manufactured for one batch may be missed.

Corrective action/s to the Root Cause: We will review and do PQR for whatever not done this year and change to use 'Review by exception pathway' in the future. We will do grouping by dosage forms and set end of every year as the reviewing time. SOP will be updated accordingly.

Corrections to observed examples: SOP QA0028 Product Quality Review

Inspector's Review:

A similar deficiency was recorded at the previous routine re-inspection conducted in May 2021.

The response addresses the issue identified. The timeline for completion is acceptable. No further response is required.

Response accepted?
Yes

Follow-up required at next inspection: **Yes** – PQRs to be reviewed to ensure new process has been implemented effectively.

Major Deficiency:

2. The requirements of Clause 2.11 that newly recruited personnel should receive training appropriate to the duties assigned to them, continuing training should also be given, and its practical effectiveness should be periodically assessed, were not fully met. For example, processes for recording the effectiveness of on-the-job training had been formalised into procedures; however, the planned checklists for recording on-the-job training activities were still being developed and no records of on-the-job training were available.

Response Date: 30/04/2025

Date of completion: 31/05/2025

Identified Root Cause: Previously production was preparing checklist for on-the-job training, but the job was not done nor properly passed to the following supervisors.

Corrective action/s to the Root Cause: From now on, we will use 3 batches records with supervisor justification as evidence for on-the-job training. SOP will be updated accordingly.

Corrections to observed examples: SOP QA0004 Training Program

Inspector's Review:
A similar deficiency was recorded concerning on-the-job training at previous routine re-inspections, including that conducted in May 2021

The response addresses the issue identified. The timeline for completion is acceptable. No further response is required.

Response accepted?
Yes

Follow-up required at next inspection: **Yes** – Processes for recording OTJ training to be reviewed to ensure new process has been implemented effectively.

Other deficiencies
Please note : A CAPA plan is required as evidence for "other" deficiencies. As a minimum this should include corrections to observed examples, and due date for completion of actions. A deficiency may be "other" either because it is judged as minor, or because there is insufficient information to classify it as major or critical, therefore manufacturers are encouraged to perform root-cause-analysis to determine the severity and extent of the deficiency and determine appropriate actions to address the deficiency. See headings below to be used for the response.

Other Deficiency:

3. The requirements of Annex 15 §10.9 that where campaign manufacture is carried out, the impact on the ease of cleaning at the end of the campaign should be considered and the maximum length of a campaign (in time and/or number of batches) should be the basis for cleaning validation exercises was not fully met. For example, cleaning validation protocols associated with the extension of campaign manufacturing activities, outlined in Quality Incident report, QID 24124, did not specify hard to clean locations on equipment, which could be impacted by the extended campaign length, to ensure these were reviewed for visual cleanliness and microbiological build-up.

Response Date: 01/05/2025

Date of completion: 09/05/2025

Corrections: Visual inspection on hard to clean locations will be added to the validation protocols.

Inspector's Review:
The response addresses the issue identified. No further response is required.

Response accepted?
Yes

Follow-up required at next inspection: No specific follow up required.

Other Deficiency:

4. The requirements of Annex 15 §11.4 concerning change control, that quality risk management should be used to evaluate planned changes to determine the potential impact on product quality, pharmaceutical quality systems, documentation, validation, regulatory status, calibration, maintenance and on any other system to avoid unintended consequences, and to plan for any necessary process validation, verification or requalification efforts, had not been fully implemented. For example, new product introduction processes did not consistently evaluate the need for process validation, nor formally evaluate whether the new product should be included in the site's on-going stability program. For example, regarding Change Control CC24163 for the transfer of Wonderland Capsules from GMP Pharmaceuticals Girraween site to the Huntingwood site,
    a. CC24163 did not identify process validation as a requirement, nor was there an evaluation recorded to ensure the new product was represented by the existing process validation product groups.
    b. CC24163 did not evaluate the need for an on-going stability study for the new product. It is acknowledged that on-going stability for this product was underway at the Girraween site; however, this was not documented in the change control and it was unclear whether manufacturing processes at the Huntingwood site would be comparable to those used at the Girraween site.

Response Date: 01/05/2025

Date of completion: 09/05/2025

Corrections: In the following change controls, we will tick all the required jobs and justify if it is not required instead of just leaving it blank.

Inspector's Review:
The response addresses the issue identified. No further response is required.

Response accepted?
Yes

Follow-up required at next inspection: No specific follow up required.

Other Deficiency:

5. The requirements of clause 3.19 that storage areas should be designed or adapted to ensure good storage conditions, [. . .] they should be clean and dry and maintained within acceptable temperature limits, and where special storage conditions are required (e.g. temperature, humidity) these should be provided, checked and monitored, were not fully met. For example, the warehouse temperature in the locations used for storage of gelatine capsule shells were not specifically monitored. The warehouse temperatures were monitored at the 'worst case' locations and temperature excursions were only actioned when temperatures were above 30 °C. There was no evidence available to demonstrate the storage locations for gelatine capsule shells would remain at or below 25 °C, as required by the special storage conditions of the material. The temperature records indicated the 'worst case' locations were above 25 °C (and below 30 °C) on multiple occasions during January and February 2025.

Response Date: 01/05/2025

Date of completion: 01/05/2025

Corrections: Hard shell capsules will be stored there until winter finish. They will be relocated to the warehouse close to office, which has air conditioner to make sure the temperature is below 25 °C.

Inspector's Review:
The response addresses the issue identified. No further response is required.

Response accepted?
Yes

Follow-up required at next inspection: No specific follow up required.

Other Deficiency:

6. The requirements of clause 5.19 that cross-contamination should be prevented by attention to design of the premises and equipment as described in Chapter 3 of the PIC/S Guide, and this should be supported by attention to process design and implementation of any relevant technical or organizational measures, including effective and reproducible cleaning processes to control risk of cross-contamination, were not fully met. For example, wash bays on both the mezzanine level and ground floors of the Tableting/Dry Powder Suite were noted to have black residue on some horizontal surfaces within the wet areas of the wash bay. The residue was present in/on sealant between wall panels and floor coving, and upon multiple horizontal ledges around the wash bay enclosures.

Response Date: 01/05/2025

Date of completion: 31/05/2025

Corrections: Swab test has been performed and confirmed it is mold. We have replaced the seal of the wash bay downstairs and will replace the rest wash bays as well. Meanwhile we are searching for antimicrobial seal to prevent it happening in the future.

Inspector's Review:
The response addresses the issue identified. The inspector acknowledges that equipment was dried and stored in areas separate from wash bays. No further response is required.

Response accepted?
Yes

Follow-up required at next inspection: No specific follow up required.

Other Deficiency:

7. The requirements of clause 5.21 regarding technical measures required to control risks for cross-contamination were not fully met as evidenced by the following,
    a. Appropriate use of air-locks and pressure cascade to confine potential airborne contaminant within a specified area were not effectively implemented (clause 5.21 (x) Technical Measures). For example, the pressure gauge reading for the wash bay on the mezzanine level of the Tableting/Dry Powder Suite indicated the pressure differential of the wash bay was positive to the central staging area of the mezzanine. This was not compliant with the facility design.
    b. On-going monitoring and preventative maintenance of the HVAC did not minimise the risks of contamination caused by recirculation or re-entry of untreated or insufficiently treated air (clause 5.21 (xi) Technical Measures). For example, confirmation of HEPA filter integrity in AHUs across the facility were limited to visual checks; however, this was not adequate to determine whether the HEPA filters had been perforated. HEPA filter integrity was a critical component of the sites HVAC design as the on-going monitoring program of room pressure differentials had no upper pressure limits, and AHUs had no pressure monitoring across their filter banks.

Response Date: 02/05/2025

Date of completion: 02/05/2025

Corrections: We found the root cause that pressure from corridor is too strong. The exhaust in wash bay cannot release the pressure in time, so the air accumulated in wash bay, leading to OOS on pressure difference. Engineers reduced the air supply and fixed the problem. So, we think it is not related to HEPA filter.

Inspector's Review:
The response addresses the issue identified. No further response is required.

Response accepted?
Yes

Follow-up required at next inspection: No specific follow up required.

TGA to complete		
Lead inspector sign off once all deficiencies are closed out	**Name:**	**Date:**
	s22 [redacted]	6/5/2025

From: s22
To:
Cc:
Subject: Re: TGA Post Inspection Letter - GMP Pharmaceuticals - Huntingwood - April 2025 [SEC=OFFICIAL]
Date: Monday, 5 May 2025 3:37:43 PM
Attachments: image001.png
image002.png
image003.png
image004.gif
image005.png
image006.png
image007.jpg
Outlook-http gmp.png
Outlook-http gmp
TGA Close Out Record - GMP Pharmaceuticals - Huntingwood - April 2025.docx

---

Hi s22

Please find the filled close-out report. Please feel free to contact me if you have any question. Thank you.

s22 | **QA Manager**

P: s22 | **M**: s22
E: s22 @gmp.com.au | www.gmp.com.au

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New South Wales 2148
Australia

Global Headquarters
60 Huntingwood Drive, Huntingwood NSW 2148

http://gmp.com.au/wp-content/uploads/2019/08/GMP_NewEmailSignature_botBar.jpg

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From: s22 @health.gov.au>
Sent: 11 April 2025 14:28
To: s22 @gmp.com.au>
Cc: s22 @gmp.com.au>
Subject: TGA Post Inspection Letter - GMP Pharmaceuticals - Huntingwood - April 2025 [SEC=OFFICIAL]

Dear s22

Please find attached the Post Inspection Letter (PIL) for the surveillance re-inspection that took place at GMP Pharmaceuticals Huntingwood premises on 3 – 4 April 2025.

I have also included a pre-populated Close Out Record, which you can use to record your responses.

As discussed at the closing meeting, you are requested to provide a description of your proposed corrective actions and a timeframe for completion if unable to complete them prior to responding to me. Objective evidence is **not** required for the deficiencies identified.

You are requested to provide your response to me by **9 May 2025**.

Thank you again for your assistance and hospitality throughout the inspection. I look forward to reviewing your response once it becomes available in the next month or so. Please do not hesitate to contact me should you need clarification regarding the inspection or the PIL.

Could you please send me a brief email as soon as you receive this message to let me know the attachments arrived to you.

Regards
s22

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Post: PO Box 100, Woden ACT 2606 Australia
www.tga.gov.au

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

This is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met

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From: s22
Sent: Friday, 4 April 2025 1:55 PM
To: s22 @gmp.com.au>
Cc: s22 @gmp.com.au>
Subject: TGA Inspection closing meeting summary - GMP Pharmaceuticals - Huntingwood - April 2025 [SEC=OFFICIAL]

Dear s22

Please find attached the closing meeting summary for the inspection.

Regards
s22

s22 (she/they)
Senior Inspector
Inspections and Compliance | Manufacturing Quality Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s22 @health.gov.au
Location: Remote
Post: PO Box 100, Woden ACT 2606 Australia
www.tga.gov.au

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---

From: s22 @gmp.com.au>
Sent: Wednesday, 2 April 2025 3:12 PM
To: s22 @health.gov.au>
Cc: s22 @gmp.com.au>
Subject: Re: Inspection plan for Huntingwood TGA Audit [SEC=OFFICIAL]

Hi s22

Well received. Thank you. See you tomorrow.

s22 | QA Manager
s22
E: s22 @gmp.com.au | www.gmp.com.au

14 Amax Avenue,
GIRRAWEEN
New South Wales 2145
Australia

60 Huntingwood Drive,
HUNTINGWOOD
New South Wales 2148
Australia

Global Headquarters
60 Huntingwood Drive, Huntingwood NSW 2148

From: s22 @health.gov.au>
Sent: 02 April 2025 14:53
To: s22 @gmp.com.au>
Cc: s22 @gmp.com.au>
Subject: Inspection plan for Huntingwood TGA Audit [SEC=OFFICIAL]

Dear s22

My apologies for attaching the incorrect version of the plan to my previous email.

Please use the one attached here for this week's inspection.

Regards
s22

s22 (she/they)
Senior Inspector
Inspections and Compliance | Manufacturing Quality Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s22 @health.gov.au
Location: Remote
Post: PO Box 100, Woden ACT 2606 Australia
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---

From: s22
Sent: Wednesday, 2 April 2025 2:48 PM
To: s22 g@gmp.com.au>
Cc: s22 @gmp.com.au>
Subject: RE: Required Documents for Huntingwood TGA Audit [SEC=OFFICIAL]

Dear s22

Please find attached the plan for this week's inspection. We can discuss the plan during the opening meeting and adjust as required by staff availability.

I will be at the Huntingwood site by 9.30 AM tomorrow.

Regards
s22

s22 (she/they)
Senior Inspector
Inspections and Compliance | Manufacturing Quality Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s22 @health.gov.au
Location: Remote
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From: s22
Sent: Tuesday, 25 March 2025 2:20 PM
To: s22 @gmp.com.au>
Cc: s22 @gmp.com.au>
Subject: RE: Required Documents for Huntingwood TGA Audit [SEC=OFFICIAL]

Dear s22

Thank you providing the requested documents. All are well received.

Regards
s22

s22 (she/they)
Senior Inspector
Inspections and Compliance | Manufacturing Quality Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
s22 @health.gov.au
Location: Remote
Post: PO Box 100, Woden ACT 2606 Australia
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independent legal advice to ensure that all of the legislative requirements are met

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From: s22 [redacted] @gmp.com.au>
Sent: Monday, 24 March 2025 5:10 PM
To: s22 [redacted] @health.gov.au>
Cc: s22 [redacted] @gmp.com.au>
Subject: Required Documents for Huntingwood TGA Audit

Hi s22 [redacted],

Please find required documents for Huntingwood site audit.
Our production manager, s22 [redacted], just left GMP the week before last week, so our site master file did not capture the change. Related change control is attached.
Please feel free to contact me if you have any question. Thank you.

s22 [redacted] | **QA Manager**

s22 [redacted]

s22 [redacted] @gmp.com.au |
www.gmp.com.au

14 Amax Avenue, GIRRAWEEN New South Wales 2145 Australia

60 Huntingwood Drive, HUNTINGWOOD New South Wales 2148 Australia

Global Headquarters
60 Huntingwood Drive, Huntingwood NSW 2148

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

s22
Quality Manager
GMP Pharmaceuticals Pty Limited
60 Huntingwood Drive
Huntingwood
NSW 2148

Our Reference: PH23/20896

Dear s22

Subject: GMP Surveillance Inspection of GMP Pharmaceuticals Pty Limited

Please find attached the inspection report for the surveillance inspection that took place at GMP Pharmaceuticals Pty Limited's Huntingwood facility on 3 – 4 April 2025.

Your response(s) to the deficiencies reported in the post inspection letter have been evaluated and have been accepted. Effective implementation will be reviewed at the next GMP inspection.

You should note that assessments made during Surveillance Inspections are based on a random and limited examination and verification of the manufacturer's documents. This inspection report does not therefore claim to be a complete evaluation of all manufacturing operations performed at your site, and does not release you from the obligation to rectify deficiencies that have not been identified or stated herein.

Should you have any questions regarding the inspection, please do not hesitate to contact me.

Yours sincerely

Signed and authorised by

s22
Senior GMP Inspector
Manufacturing Quality Branch

Date: 30 May 2025
Tel: s22
E-mail: s22 @health.gov.au

Surveillance Inspection Report

Manufacturer:	GMP Pharmaceuticals Pty Limited
Inspected site/s:	60 Huntingwood Drive, Huntingwood NSW 2148
Manufacturer information:	Refer to previous inspection report at XX-XXXXXXX
Activities carried out by manufacturer:	☑ Manufacture of finished medicinal product ☐ Manufacture of intermediate or bulk ☐ Packaging ☐ Laboratory testing ☐ Release for supply ☐ Manufacture of Active Pharmaceutical Ingredient ☐ Other:
Type of inspection:	☑ Re-inspection ☑ Surveillance inspection ☐ Remote inspection ☐ Hybrid inspection Applicable sections of the *Therapeutic Goods Act 1989*: ☑ section 40(4)(b) (re-inspection of licensed site) ☐ section 25(1)(g) (overseas in relation to registration) ☐ sections 26(1)(g), 26A(3) (overseas in relation to listing)
Scope of Inspection	Finished product manufacture of listed medicine in powder, granule, tablet and hard shell capsule dosage forms. Packaging, labelling and release for supply of listed medicine in soft gel capsule dosage forms. Storage and testing of listed medicine in all dosage forms.
Inspection date/s:	3 – 4 April 2025
Inspector:	s22 [redacted]
Manufacturing Standard used:	PIC/S Guide to Good Manufacturing Practice for Medicinal Products, Part I (PE 009-16)
References:	Manufacturing Licence number: Inspection tracking number: MI-2023-LI-03211-1 File reference number/s: PH22/23765 (inspection file), E22-613342 (licence file)

Personnel met during the inspection

s22 QA Manager
s22 Quality & Compliance Manager

Inspected areas, findings and observations

Refer to Site Master File, SMF001 version 8, effective December 2025, for information of site activities.

Major changes since the previous inspection:

- Multiple new products introduced to site
- Changes to key personnel at Huntington; replaced by suitably experienced staff from GMP Pharmaceuticals Girraween complex
- Upgrade or replacement to some ancillary production and laboratory equipment

Future Planned Changes: None discussed

Quality Management	
Subject area inspected	**Compliance outcome / comments**
Review of actions taken since previous inspection	Deficiencies 1 & 2 recorded at this inspection were similar to deficiencies recorded at the previous routine re-inspections of May 2021.
Product Quality Reviews	Refer to deficiency 1. A similar deficiency was recorded at the previous routine re-inspection conducted in May 2021.
Change Management	Refer to deficiency 4
Complaints management	No deficiencies identified
Deviation, non-conformance and CAPA management	No deficiencies identified
Internal Audits	No deficiencies identified
Batch Record Review and Batch Release	No deficiencies identified
Training	Refer to deficiency 2. A similar deficiency was recorded concerning on-the-job training at previous routine re-inspections, including that conducted in May 2021.
Materials Management	
Subject area inspected	**Compliance outcome / comments**
Warehousing	Refer to deficiency 5

Starting Materials	No deficiencies identified
Production System	
Subject area inspected	**Compliance outcome / comments**
Production - Formulation Areas	Refer to deficiency 6
Production - Manufacture/Filling	No deficiencies identified
Production – Labelling/ Packaging	No deficiencies identified
Validation/Qualification	
Subject area inspected	**Compliance outcome / comments**
Process Validation	Refer to deficiency 4a
Cleaning Validation	Refer to deficiency 3
Computer System Validation	No deficiencies identified
Facilities and Equipment	
Subject area inspected	**Compliance outcome / comments**
HVAC	Refer to deficiency 7
Water Systems	No deficiencies identified
Quality Control	
Subject area inspected	**Compliance outcome / comments**
Equipment Calibration/Maintenance/ Operation	No deficiencies identified
Test results	No deficiencies identified

List of Deficiencies observed during the inspection

Critical deficiencies:

None observed

Major deficiencies:

1. The requirement of Clause 1.10 that regular periodic or rolling quality reviews of all authorised medicinal products, including export only products, should be conducted with the objective of verifying the consistency of the existing process, the appropriateness of current specifications for both starting materials and finished product, to highlight any trends and to identify product and process improvements; and these product quality reviews (PQRs) should normally be conducted and documented annually, were not fully met. For example, there were no formal processes in place to ensure PQRs were available for all authorised medicinal products manufactured at site, and to ensure PQRs were conducted annually (or every 2 years for low volume products). The inspector noted that the available PQRs may represent the full product range; however, GMP Pharmaceuticals approved process was to conduct individual, product based PQRs, rather than using a grouped product approach.

2. The requirements of Clause 2.11 that newly recruited personnel should receive training appropriate to the duties assigned to them, continuing training should also be given, and its practical effectiveness should be periodically assessed, were not fully met. For example, processes for recording the effectiveness of on-the-job training had been formalised into procedures; however, the planned checklists for recording on-the-job training activities were still being developed and no records of on-the-job training were available.

Other deficiencies:

3. The requirements of Annex 15 §10.9 that where campaign manufacture is carried out, the impact on the ease of cleaning at the end of the campaign should be considered and the maximum length of a campaign (in time and/or number of batches) should be the basis for cleaning validation exercises was not fully met. For example, cleaning validation protocols associated with the extension of campaign manufacturing activities, outlined in Quality Incident report, QID 24124, did not specify hard to clean locations on equipment, which could be impacted by the extended campaign length, to ensure these were reviewed for visual cleanliness and microbiological build-up.

4. The requirements of Annex 15 §11.4 concerning change control, that quality risk management should be used to evaluate planned changes to determine the potential impact on product quality, pharmaceutical quality systems, documentation, validation, regulatory status, calibration, maintenance and on any other system to avoid unintended consequences, and to plan for any necessary process validation, verification or requalification efforts, had not been fully implemented. For example, new product introduction processes did not consistently evaluate the need for process validation, nor formally evaluate whether the new product should be included in the site's on-going stability program. For example, regarding Change Control CC24163 for the transfer of Wonderland Capsules from GMP Pharmaceuticals Girraween site to the Huntingwood site,
    a. CC24163 did not identify process validation as a requirement, nor was there an evaluation recorded to ensure the new product was represented by the existing process validation product groups.
    b. CC24163 did not evaluate the need for an on-going stability study for the new product. It is acknowledged that on-going stability for this product was underway at the Girraween site; however, this was not documented in the change control and it was unclear whether manufacturing processes at the Huntingwood site would be comparable to those used at the Girraween site.

5. The requirements of clause 3.19 that storage areas should be designed or adapted to ensure good storage conditions, [. . .] they should be clean and dry and maintained within acceptable temperature limits, and where special storage conditions are required (e.g. temperature, humidity) these should be provided, checked and monitored, were not fully met. For example, the warehouse temperature in the locations used for storage of gelatine capsule shells were not specifically monitored. The warehouse temperatures were monitored at the 'worst case' locations and temperature excursions were only actioned when temperatures were above 30 °C. There was no evidence available to demonstrate the storage locations for gelatine capsule shells would remain at or below 25 °C, as required by the special storage conditions of the material. The temperature records indicated the 'worst case' locations were above 25 °C (and below 30 °C) on multiple occasions during January and February 2025.

6. The requirements of clause 5.19 that cross-contamination should be prevented by attention to design of the premises and equipment as described in Chapter 3 of the PIC/S Guide, and this should be supported by attention to process design and implementation of any relevant technical or organizational measures, including effective and reproducible cleaning processes to control risk of cross-contamination, were not fully met. For example, wash bays on both the mezzanine level and ground floors of the Tableting/Dry Powder Suite were noted to have black residue on some horizontal surfaces within the wet areas of the wash bay. The residue was present in/on sealant between wall panels and floor coving, and upon multiple horizontal ledges around the wash bay enclosures.

7. The requirements of clause 5.21 regarding technical measures required to control risks for cross-contamination were not fully met as evidenced by the following,
    a. Appropriate use of air-locks and pressure cascade to confine potential airborne contaminant within a specified area were not effectively implemented (clause 5.21 (x) Technical Measures). For example, the pressure gauge reading for the wash bay on the mezzanine level of the Tableting/Dry Powder Suite indicated the pressure differential of the wash bay was positive to the central staging area of the mezzanine. This was not compliant with the facility design.
    b. On-going monitoring and preventative maintenance of the HVAC did not minimise the risks of contamination caused by recirculation or re-entry of untreated or insufficiently treated air (clause 5.21 (xi) Technical Measures). For example, confirmation of HEPA filter integrity in AHUs across the facility were limited to visual checks; however, this was not adequate to determine whether the HEPA filters had been perforated. HEPA filter integrity was a critical component of the sites HVAC design as the on-going monitoring program of room pressure differentials had no upper pressure limits, and AHUs had no pressure monitoring across their filter banks.

Comments
None

Summary and conclusions

Assessment of manufacturer's responses
A response to the deficiencies reported to the manufacturer was received on 5 May 2025. The manufacturer's corrective actions have been evaluated and accepted, based on the agreement that all corrective actions will be carried out as described in the inspection close out correspondence.

Final evaluation and recommendations:
1. The manufacturer operates in accordance with the relevant GMP requirements.

2. TGA records have been updated to show a final compliance rating of your facility of A2: satisfactory compliance with the manufacturing standard established under the *Therapeutic Goods Act 1989*.

3. The next re inspection is expected to be performed within 30 months.

4. The duration of the next inspection is estimated at this time to be 4 days and will be conducted as a Full Inspection.

Signed and authorised by

s22
Senior Inspector
Manufacturing Quality Branch

Date: 30 May 2025
Mobile: s22
E-mail: s22 @health.gov.au

Australian Government
Department of Health
Therapeutic Goods Administration

s22
GMP Pharmaceuticals Pty Limited
60 Huntingwood Drive
Huntingwood
NSW 2148

Ref: PH23/20896

RE: **The *Therapeutic Goods Act 1989***
Surveillance inspection of GMP Pharmaceuticals Pty Limited
Inspection Tracking Number MI-2023-LI-03211-1

Dear s22,

I would like to thank you and s22 for the courtesy and attention extended during the inspection conducted of GMP Pharmaceuticals Pty Limited on 3 – 4 April 2025.

During the inspection, a number of inspection findings, listed as deficiencies in the appendix to this letter, have been identified that indicate a departure from acceptable GMP standards, and these items require prompt resolution.

You are requested to respond to the deficiencies recorded below within four (4) weeks from the date of this letter. A standard form (in Word) to prepare the response has been issued with this letter. The preferable format for your response is:

- For the response form (Close out record): as a Word document that is not marked as final;
- For all deficiencies categorised as 'critical' or 'major' a CAPA plan should be submitted that includes root cause analysis, corrective action/s to the root cause, preventative action/s to the root cause, corrections to observed examples, and due date for completion of actions.
- For the deficiencies categorised as 'other', a CAPA plan is not required; however, the response date, the correction and due date for completion are required to be provided.

All correspondence regarding the inspection should be addressed to me at the email address below.

Yours sincerely

Signed and authorised by

s22
Senior Inspector
Manufacturing Quality Branch
Date: 27 April 2025

Phone: s22
E-mail: s22@health.gov.au

APPENDIX

Scope of inspection

The inspection was conducted to review on-going compliance to the PIC/S Guide to GMP for Medicinal Products (PE-009-16) for operations at GMP Pharmaceuticals Pty Limited's Huntingwood facility via surveillance inspection, as per the following manufacturing table and licence conditions below:

Manufacturing Type	Sterility	Dosage Form	Product Code	Manufacturing Step
Medicine manufacture	Non Sterile	All Dosage Forms	Listed Therapeutic Good	Storage
Medicine manufacture	Non Sterile	All Dosage Forms	Listed Therapeutic Good	Testing
Medicine manufacture	Non Sterile	Powders Group	Listed Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Granules Group	Listed Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms - Tablets	Listed Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Capsule, hard	Listed Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Capsule, soft	Listed Therapeutic Good	Packaging, Labelling and Release for Supply

Condition: This licence does not authorise the manufacture of medicines listed for export that include substances at a level only permitted in medicines contained within schedules 2, 3, 4 & 8 of the Poisons Standard.

List of Deficiencies observed during the inspection

Critical deficiencies:

None observed

Major deficiencies:

1. The requirement of Clause 1.10 that regular periodic or rolling quality reviews of all authorised medicinal products, including export only products, should be conducted with the objective of verifying the consistency of the existing process, the appropriateness of current specifications for both starting materials and finished product, to highlight any trends and to identify product and process improvements; and these product quality reviews (PQRs) should normally be conducted and documented annually, were not fully met. For example, there were no formal processes in place to ensure PQRs were available for all authorised medicinal products manufactured at site, and to ensure PQRs were conducted annually (or every 2 years for low volume products). The inspector noted that the available PQRs may represent the full product range; however, GMP Pharmaceuticals approved process was to conduct individual, product based PQRs, rather than using a grouped product approach.

   A similar deficiency was recorded at the previous routine re-inspection conducted in May 2021.

2. The requirements of Clause 2.11 that newly recruited personnel should receive training appropriate to the duties assigned to them, continuing training should also be given, and its practical effectiveness should be periodically assessed, were not fully met. For example, processes for recording the effectiveness of on-the-job training had been formalised into procedures; however, the planned checklists for recording on-the-job training activities were still being developed and no records of on-the-job training were available.

A similar deficiency was recorded concerning on-the-job training at previous routine re-inspections, including that conducted in May 2021.

Other deficiencies:

3. The requirements of Annex 15 §10.9 that where campaign manufacture is carried out, the impact on the ease of cleaning at the end of the campaign should be considered and the maximum length of a campaign (in time and/or number of batches) should be the basis for cleaning validation exercises was not fully met. For example, cleaning validation protocols associated with the extension of campaign manufacturing activities, outlined in Quality Incident report, QID 24124, did not specify hard to clean locations on equipment, which could be impacted by the extended campaign length, to ensure these were reviewed for visual cleanliness and microbiological build-up.

4. The requirements of Annex 15 §11.4 concerning change control, that quality risk management should be used to evaluate planned changes to determine the potential impact on product quality, pharmaceutical quality systems, documentation, validation, regulatory status, calibration, maintenance and on any other system to avoid unintended consequences, and to plan for any necessary process validation, verification or requalification efforts, had not been fully implemented. For example, new product introduction processes did not consistently evaluate the need for process validation, nor formally evaluate whether the new product should be included in the site's on-going stability program. For example, regarding Change Control CC24163 for the transfer of Wonderland Capsules from GMP Pharmaceuticals Girraween site to the Huntingwood site,
    a. CC24163 did not identify process validation as a requirement, nor was there an evaluation recorded to ensure the new product was represented by the existing process validation product groups.
    b. CC24163 did not evaluate the need for an on-going stability study for the new product. It is acknowledged that on-going stability for this product was underway at the Girraween site; however, this was not documented in the change control and it was unclear whether manufacturing processes at the Huntingwood site would be comparable to those used at the Girraween site.

5. The requirements of clause 3.19 that storage areas should be designed or adapted to ensure good storage conditions, [. . .] they should be clean and dry and maintained within acceptable temperature limits, and where special storage conditions are required (e.g. temperature, humidity) these should be provided, checked and monitored, were not fully met. For example, the warehouse temperature in the locations used for storage of gelatine capsule shells were not specifically monitored. The warehouse temperatures were monitored at the 'worst case' locations and temperature excursions were only actioned when temperatures were above 30 °C. There was no evidence available to demonstrate the storage locations for gelatine capsule shells would remain at or below 25 °C, as required by the special storage conditions of the material. The temperature records indicated the 'worst case' locations were above 25 °C (and below 30 °C) on multiple occasions during January and February 2025.

6. The requirements of clause 5.19 that cross-contamination should be prevented by attention to design of the premises and equipment as described in Chapter 3 of the PIC/S Guide, and this should be supported by attention to process design and implementation of any relevant technical or organizational measures, including effective and reproducible cleaning processes to control risk of cross-contamination, were not fully met. For example, wash bays on both the mezzanine level and ground floors of the Tableting/Dry Powder Suite were noted to have black residue on some horizontal surfaces within the wet areas of the wash bay. The residue was present in/on sealant between wall panels and floor coving, and upon multiple horizontal ledges around the wash bay enclosures.

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    a. Appropriate use of air-locks and pressure cascade to confine potential airborne contaminant within a specified area were not effectively implemented (clause 5.21 (x) Technical Measures). For example, the pressure gauge reading for the wash bay on the mezzanine level of the Tableting/Dry Powder Suite indicated the pressure differential of the wash bay was positive to the central staging area of the mezzanine. This was not compliant with the facility design.
    b. On-going monitoring and preventative maintenance of the HVAC did not minimise the risks of contamination caused by recirculation or re-entry of untreated or insufficiently treated air (clause 5.21 (xi) Technical Measures). For example, confirmation of HEPA filter integrity in AHUs across the facility were limited to visual checks; however, this was not adequate to determine whether the HEPA filters had been perforated. HEPA filter integrity was a critical component of the sites HVAC design as the on-going monitoring program of room pressure differentials had no upper pressure limits, and AHUs had no pressure monitoring across their filter banks.

DEFINITIONS

Marketing Authorisation

Compliance with regulatory requirements specified on the ARTG and any other requirements imposed by a relevant Delegate of Secretary upon product listing or registration.

Examples of regulatory requirements include but not limited to the following: compliance with registered formulations, special storage and transportation conditions, shelf life, labelling, batch release testing requirements etc.

Critical Deficiency

A deficiency in a practice or process that has produced, or may result in, a significant risk of producing a product that is harmful to the user. Also occurs when it is observed that the manufacturer has engaged in fraud, misrepresentation or falsification of products or data.

Major Deficiency

A non-critical deficiency that:

- has produced or may produce a product which does not comply with its marketing authorisation; and/or
- indicates a major deviation from the Code of GMP; and/or
- indicates a major deviation from the terms of the manufacturing licence or GMP approval (overseas manufacturers); and/or
- indicates a failure to carry out satisfactory procedures for release of batches; and/or
- indicates a failure of the person responsible for QA/QC to fulfil his/her duties; and/or
- consists of several other deficiencies, none of which on its own may be major, but which may together represent a major deficiency and should be explained and reported as such.

Other Deficiency

A deficiency that cannot be classified as either critical or major but indicates a departure from good manufacturing practice.

A deficiency may be "other" either because it is judged as minor, or because there is insufficient information to classify it as major or critical.

One-off minor lapses or less significant issues are usually not formally reported but are brought to the attention of the manufacturer.

Note:

1. Classification of a deficiency is based on the assessed risk level and may vary depending on the nature of products manufactured, e.g in some circumstances an example of major deficiency may be categorised as critical.
2. A deficiency that was reported at a previous inspection and not corrected may be reported in a higher classification.

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Manufacturing
Quality
Branch

MQB - Form

FORM 5.2.a	Inspection Record		
Comes Under	SOP 5.2 – Inspection Preparation and Planning		
Process Owner	Director, Inspections	Authorised by	Quality Manager
Date Issued	7 June 2024	Version #	3.3

Section 1 – Inspection Preparation

Lead Inspector to complete this section when preparing to conduct an inspection, following SOP 5.2 – "Inspection Preparation and Planning".

Parameter:	Entry:
MIS Tracking Number:	MI-2023-LI-03211-1
Manufacturer Name:	GMP Pharmaceuticals Pty Limited
Date(s) of Inspection:	3 – 4 April 2025
Inspection Type(s):	☒Medicines ☐APIs ☐Bloods ☐Cellular Therapies ☐Tissues ☐Veterinary ☐Gene Therapies ☐Other (specify): ☐Re-inspection ☐Initial ☐Reduced scope ☒Surveillance ☐Special (select): ☐Close-out ☐Compliance
Inspection Method:	☒On-site ☐Remote ☐Hybrid
Sterility Status:	☒Non-sterile ☐Sterile

Inspection Scope: (SOP 5.2 Appendix 2)	Full product manufacture of non-sterile listed medicines in the form of tablets, hard capsules, powders and granules. Packaging, labelling & RFS of listed medicine soft gel capsules Storage of all non-sterile listed medicines dosage forms Testing of all non-sterile listed medicines dosage forms The inspection is a surveillance inspection with **reduced scope**, as detailed in the inspection plan (and outlined below in red)
2 items from each of the 5 streams	☐Stream 1 – Materials Control Warehousing ❒ GMP Contract agreements ❒ Control of storage areas ❒ Rejects Control ❒ Cleaning/Housekeeping ❒ Temperature/humidity monitoring ❒ Raw Materials/Bulk Materials ❒ Finished Goods ❒ Supplier Evaluation/API Audits ❒ Inventory Management System ❒ Returned goods ❒ Retention/Reference Samples ❒ Status Control-Identification/Traceability ❒ Waste Disposal ❒ Dispatch/Handling/Traceability Starting Materials ❒Receipt, Quarantine/Inspection/Testing ❒Control of utensils ❒Approval for use ❒Picking/Dispensing ❒Control of pre-printed packaging packaging/components ❒ Sampling area/Plans ❒ Retention Samples ❒ Cleaning/Housekeeping ❒ Control of Components ❒ Sampling/Approval of

☐ Stream 2 – Production System

Dispensing Areas

- ❒ Materials Flow
- ❒ Room grading
- ❒ Control of utensils
- ❒ Cleaning/Housekeeping
- ❒ Gowning/Access
- ❒ Equipment logs
- ❒ Retention Samples
- ❒ Containment

Production - Formulation Areas

- ❒ Materials Flow
- ❒ Room grading
- ❒ Water supply
- ❒ Preparation of solutions
- ❒ Solution Filtration
- ❒ IPQC testing
- ❒ Transfer of Bulk solutions to filling
- ❒ Gowning/Access
- ❒ Equipment logs
- ❒ Equipment CIP/SIP
- ❒ Mixing/Blending
- ❒ Bulk storage/monitoring
- ❒ Environmental Monitoring
- ❒ Batch record formats/entries

Production - Manufacture/Filling

- ❒ Process flow
- ❒ Batch record formats/entries
- ❒ Temp/Humidity/Pressure differentials
- ❒ Area condition/finishes
- ❒ Equipment CIP/SIP
- ❒ Dress codes/gowning/personal hygiene
- ❒ Cleaning procedures/records
- ❒ Contamination control – air/layout

- ❒ In-process checks/sampling
- ❒ Management of components

General

- ❒ Waste control
- ❒ Reconciliation
- ❒ Sampling plans (chem/micro)
- ❒ Line clearance
- ❒ Contamination control – air/layout

Production – Labelling/ Packaging

- ❒ Process flow
- ❒ Batch record formats/entries
- ❒ Temp/Humidity/Pressure differentials
- ❒ Area condition/finishes
- ❒ Labelling/Coding
- ❒ Reconciliation of components
- ❒ Check weighers/VISY
- ❒ Return of unused components
- ❒ Dress codes/gowning /personal hygiene
- ❒ Cleaning procedures/records
- ❒ Room grading
- ❒ Packaging Equipment
- ❒ IPQC checks & records
- ❒ Line clearance
- ❒ Rejected units
- ❒ Batch & Product displayed

IPC Laboratory

- ❒ Equipment calibrated/maintained
- ❒ Completion of Batch records
- ❒ Procedures/Records
- ❒ Cleaning procedures/records

☐ Stream 3 – Validation/ Qualification

- ❒ VMP (Schedule)
- ❒ Equipment List
- ❒ Document formats
- ❒ Equipment Qualification
- ❒ Revalidation

- ❒ Process validation and ongoing process verification
- ❒ Cleaning Validation/HBEL
- ❒ Computerised systems

- ❒ Temperature controlled areas

☐ Stream 4 – Facilities & Equipment

Review of Utilities & Services

❒ Preventive Maintenance ❒ Calibration
❒ Pest Control ❒ Waste Disposal

HVAC

❒ Area Classifications ❒ P&ID's
❒ Specifications/Design/Construction ❒ Filtration supply/return/exhaust
❒ Pressures/Containment strategy ❒ Room certification/airflow visualisation
❒ Monitoring/Control/Testing/Trends ❒ Handling of alarms and trending
❒ Operation/Checks/Cleaning ❒ Validation system/BMS/Alarms
❒ Power failure ❒ Equipment calibration and maintenance
❒ Environmental Monitoring

Water Systems

❒ Use / SOPs ❒ P&ID's
❒ Specifications/Design/Construction ❒ Sanitisation
❒ Monitoring/Control/Testing/Trends ❒ Operation/Checks/Cleaning
❒ Validation ❒ Equipment calibration and maintenance

Critical Production Equipment

❒ Use / SOPs ❒ P&ID's
❒ Specifications/Design/Construction ❒ Sterilisation/Sanitisation
❒ Monitoring/Control/Testing ❒ Operation/Checks/Cleaning
❒ Validation ❒ Equipment calibration and maintenance

Compressed air/gasses/vacuum (Natural Gas/O_2/N_2)

❒ Use / SOPs ❒ P&ID's
❒ Specifications/Design/Construction ❒ Sterilisation/Sanitisation
❒ Monitoring/Control/Testing ❒ Operation/Checks/Cleaning

❒ Validation ❒ Equipment calibration and maintenance

☐ Stream 5 – Quality Control

Chemistry

❒ Sample Preparation/Dispatch ❒ Stability
❒ Specifications and test methods
❒ Testing as per specification ❒ Test results (raw data)
❒ Method validation ❒ Reference standards
❒ Reagents/Volumetric Solutions ❒ Reference/retention samples
❒ Instruments/Equipment ❒ Equipment calibration/maintenance
❒ Equipment Qualification ❒ System suitability
❒ Water testing ❒ Personnel training
❒ Contract testing ❒ OOS/OOT Procedures
❒ Certificates of Analysis ❒ Release of results
❒ Data Management

Microbiology

❒ Sample Preparation/Dispatch ❒ Media Preparation/QC
❒ Culture collection ❒ Incubator monitoring/mapping
❒ Equipment Qualification ❒ Equipment calibration/maintenance
❒ Specifications
❒ Test methods ❒ Method validation
❒ Test results (raw data/computerised systems)
❒ OOS/OOT Procedures
❒ Water testing ❒ EM/PM (viable/non-viable)
❒ Antibiotic assays
❒ Data management
❒ Sample Preparation/Dispatch
❒ Contract testing ❒ Personnel training
❒ Certificates of Analysis ❒ Release of results

Initial email contact and email notification followed up with Inspection Announcement letter	Name s22 [redacted] Date: 11/3/2025 ☒Manufacturer ☐ Sponsor
Inspection preparation conducted and recorded/filed in accordance with SOP 5.2?	☒Yes ☐No (explain)
MIS pre-inspection task completed (WI 5.2.2)	☒Yes ☐No (explain)
~~International Biological manufacturer?~~	~~☐Yes ☐N/A~~ ~~Pre-inspection hours:~~

Section 2 – Inspection Conduct/Outcome

Lead Inspector to complete this section after conducting an inspection, following SOP 5.3 – "Conducting an Inspection".

Parameter:	Entry:		
Date back in office after Inspection:	7/04/2025		
Access denied?	☒No ☐Yes (explain)		
Sampling process (WI 5.3.7) conducted?	☐ Yes ☒ No	TRIM ref #	n/a
Any areas not covered during the inspection?	☒ No ☐ Yes (explain)		
Previous inspection findings: reviewed?	☐Yes, no further issues ☐ No (explain)	☒Yes, repeat issues identified ☐N/A	
Recalls verified on site? (Form 5.1.1a):	☐Yes, no further issues ☐ No (explain)	☐Yes, issues identified ☒N/A	
Inspection conducted and recorded/filed in accordance with SOP 5.3/5.4:	☒ Yes ☐ No (explain)		
Conflict of interest: Financial or other interest in inspected company?	☒ No ☐ Yes (explain)	Were gift / meal / other hospitality / travel / entertainment, etc. provided?	☒ No ☐ Yes (explain)

Inspection outcome			
Provisional compliance rating	☐ 1st A1 rating ☐ 2nd consecutive repeat ☐ 3rd or subsequent repeat		
	☒ A2		
	☐ A3 ☐ Repeat A3		
	☐ Unacceptable		
Referred to Review Panel (SOP 5.5)	☒ No ☐ Yes	Date referred: TRIM review panel folder ref #	n/a
MIS [Audit Document] data completed (WI 5.3.8)?	☒ Yes ☐ No (explain)		
Date PIL submitted for review (WI 5.3.10):	11/04/2025		
LI comments:	☒ N/A		

Reinspection Details	
Risk Category:	☐ High ☐ Medium ☐ Low ☒ Listed
Months to next inspection:	~~(H/M/L) ☐ 12 ☐ 15 ☐ 18 ☐ 20 ☐ 24 ☐ 36~~ (Listed) ☐ 18 ☒ 30 ☐ 42 ☐ 48 Comment:
LI recommended next inspection:	Team composition: 1 inspector Duration: 4 days Reaudit raised by LI as above ~~Reduced scope inspection: ☐ Yes ☐ No If yes, what is recommended.~~ ~~For medicines:~~ ~~☐ Stream 1 Materials Control ☐ Stream 2 Production System ☐ Stream 3 Validation/ Qualification ☐ Stream 4 Facilities & Equipment ☐ Stream 5 Quality Control~~
Inspection Notes	
Record any notes relevant to the inspection that may be useful to subsequent inspections, e.g. site access, travel/transport, accommodation, isolated work, PPE/WHS concerns, language barriers, alerts etc.	☒ N/A

Section 3 – PIL Peer Review / Create re-inspection

Peer reviewer to complete this section after reviewing the PIL for compliance with WI 5.3.10 "Writing a Post-inspection Letter (PIL)" and creating a re-inspection following SOP WI 5.3.11 "Creating a re-audit in MIS".

Parameter:	Entry:
Reviewer name:	s22 [redacted]
All requirements of WI 5.3.10 met?	☒ Yes ☐ No (explain)
Any feedback on PIL to LI required?	☒ No ☐ Yes (explain)
Need to see the PIL again?	☒ No ☐ Yes (explain)
Provisional compliance rating:	☒ Agree ☐ Disagree (explain)
If disagree then changed to:	☐ N/A
Refer to Review Panel?	☒ No ☐ Yes (explain)
Reinspection raised (MIS) (WI 5.3.11):	☒ Yes ☐ No (explain) **Raised by** s 2 [redacted]
Reviewer's comments:	☐ N/A Good PIL
Lead Inspector to complete MIS Audit [Inspection] task following PIL review (WI 5.3.8):	☒ Yes ☐ No (explain)

Section 4 – Inspection Close-out & Report

Parameter:	Entry:		
Date PIL sent to manufacturer:	**11/04/2025**		
Date APVMA report sent: (for inspections performed under the MRA provisions)	☒N/A		
Date close-out report sent to manufacturer (WI 5.4.7):	**30/5/2025**		
Inspection close-out conducted and recorded/filed in accordance with SOP 5.4 & WI 5.4.6:	☒ Yes ☐ No (explain)		
~~International Biological manufacturer?~~	~~☐Yes ☐N/A~~ ~~Post inspection hours:~~		
	~~Date:~~	~~Hours:~~	
Final compliance rating:	☒As provisional ☐changed to AX If rating was changed – confirm reinspection details changed Explanation:		
Based on manufacturers response, is the duration of the next inspection sufficient? (WI 5.4.6)	☒ Yes ☐ No (explain if any additional time added) ~~**Additional time added:**~~ ~~MIS re-inspection amended: ☐ Yes~~		
Licence/certification/ clearance processing initiated:	☐ Yes ☒ No (explain)		
MIS POST Audit [Inspection] task completed (WI 5.4.3):	☐ No ☒ Yes (explain)		
Peer notified to complete Audit Completion task in MIS (WI 5.4.4)	☒ Yes ☐ No	Name of peer notified:	s22 [redacted]
e-signed (PIL, REPORT, THIS FORM) in TRIM:	☒ Yes ☐ No		