Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Office use only

Request for Laboratory Analysis

Requestor Details

Name / Phone	s22 [redacted]
Title	Compliance Officer
Section / Branch	Product Import Compliance Section (PIS), Regulatory Compliance Branch (RCB)
Email for Results Distribution	s22 [redacted]@health.gov.au

Request Information

Request Date	23/10/2024
Reference & TRIM No	RC-030392, D24-4157511
Request to	Chemistry Section

Request and Sample Information

Background Information

Suspected counterfeit (less than the declared API)

The Product and Import Compliance Section (PICS) received a referral, from Australian Border Force (ABF) in relation to the product 'Iverjohn-12 Ivermectin 12mg' tablets.

The product is not registered in the Australian Registered of Therapeutic Goods (ARTG).

PICS have particular concerns as to whether the product contains the labelled concentration/dosage of API ivermectin (12mg). This is because it has previously been tested and found to contain less than the declared amount of ivermectin, and the COA has now expired.

Sample Information

Total Number of Samples/Products Provided to Laboratories Branch	20 tablets

Please complete Appendix 1 - Sample Details

Storage Conditions	nil

Were the samples requested:

- Under Subregulation 28(5)(h) of the *Therapeutic Goods Act*? ☐ Yes ☒ No
- Under Subregulation 41FN(2) of the *Therapeutic Goods Act*? ☐ Yes ☒ No

or

- Taken by an Authorised Officer/Person under the *Therapeutic Goods Act*? ☐ Yes ☒ No

Note: Samples requested under s28(5)(h) or s41FN(2) must be received by delegate under Subregulation 26(A) of the *Therapeutic Goods Regulations.* Please discuss the requirements with the testing area

Testing Requested

Identification and estimated content of any pharmaceutical ingredients present in the sample.

Testing Timeframes

	Medicines (including vaccines and biological medicines)	Medical Devices
☐ **Urgent**	*Samples associated with a serious adverse event that has occurred and has the potential to recur. A serious adverse event is any untoward medical occurrence that, at any dose, results in the following conditions:* • death; • a life-threatening event (Note: The term 'life-threatening' in the definition of 'serious' refers to an event/reaction in which the patient was at risk of death at the time of the event/reaction; it does not refer to an event/ reaction which hypothetically might have caused death if it were more severe); • inpatient hospitalisation or results in prolongation of existing hospitalisation; • persistent or significant disability/incapacity; • a congenital anomaly/birth defect; or • a medically important event or reaction.	*Samples associated with a serious adverse event that has occurred and has the potential to recur. A serious adverse event is an event that led to the following conditions:* • death • a serious injury or serious deterioration to a patient, user or other person, including: • a life-threatening illness or injury • permanent impairment of a body function • permanent damage to a body structure; or • a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure
☐ **Priority**	Intelligence indicates that laboratory investigation is necessary to prevent a serious adverse event.	
☒ **Routine**	All other samples	
☐ **Request**	Please provide details of the need for an accelerated timeframe, including the deadline date and reason Example: Court proceedings scheduled for 29th February 2024, results will be required by 15th January 2024 to allow preparation of the case. Click or tap here to enter text.	

Target timeframes are **20** work days for Urgent samples, **40** work days for Priority samples, and **50** work days for Routine samples. Microbiology timeframes may exceed 20 work days due to incubation periods.

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Fill in the table most relevant to the sample/s requiring laboratory testing.

Devices and registered/listed products

ARTG Number	Product Name as per ARTG* (include dosage form)	Sponsor /Manufacturer	Batch and/or Serial Number	Expiry Date	Evidence Tag Number	Intended Purpose (Medical Devices only)	Device Class	LIMS Number (LB Use Only)

* if the ARTG name differs from the name on the label, include both names here and indicate which should appear on the Certificate of Analysis once testing is complete.

Unregistered and seized products

CRM Exhibit number	Evidence Bag number	Product Name	Batch Number	Expiry Date	Comments or Additional Information	LIMS Number (LB Use Only)
RC-PI-00000000000002541	**A340762827**	**Iverjohn-12 ivermectin 12mg**	SLT061	11/2026		**2410003582**

From: s22
To: s22
Cc: s22
Subject: RC-030392 - Iverjohn-12 [SEC=OFFICIAL]
Date: Thursday, 20 March 2025 11:23:25 AM
Attachments: image001.png

Good Morning

Please see the report relating to the laboratory analysis for the above investigation: D25-690301

Links to the Certificate of Analysis and photographs are located within the report.

If you have any questions about our findings, please contact me.

Regards,

s22 - Chemistry Section
Laboratories Branch

Medical Devices & Product Quality Division | Health Products Regulation Group
Australian Government Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
Location: Level 1, 1 Tindal Lane, Fairbairn, ACT
PO Box 100, Woden ACT 2606, Australia

From: s22
To:

Subject: Update: Critical decision record D25-05 - confirmed counterfeit ivermectin, new notification, and two additional products [SEC=OFFICIAL]
Date: Monday, 24 March 2025 9:21:00 PM
Attachments: image001.png
image002.png
image003.png
image004.png

Good evening team:

We still facing significant numbers of ABF holds awaiting TGA advice, which poses a variety of risks. To ease some of this pressure I have made a decision to continue our streamlined process for confirmed counterfeit ivermectin products.

- The initial decision was effective 22 October to 31 December 2024 – Issues and Decision Register **Reference D24-13**
- My previous decision was effective 19 December through to 31 March 2025 Issues and Decision Register **Reference D24-12**

I am providing delegate approval for all 42F notifications for our confirmed counterfeit ivermectin products with a new certificate from today, through to **30 June 2025**

This decision applies to only the 8 below products below, in the exact strength identified:

Iversun-12 – Project 2828
Iverguard-12 – Project 2821
Iverhuman-12 - Project 2828
Ivetab-12 - Project 2582
Covimectin-12 - Project 2854
Iverheal-12 - Project 2853

And two new products:

Iverjohn-12 – Project 2951
Ivervid-12 – Project 2992

I have updated the Work Instructions, which can be found here: Work Instruction - Counterfeit ivermectin process - WI2024-04.docx

For Triage: Where an import contains only counterfeit ivermectin, you can continue to provide ABF with the new 42F notification and adjusted/updated wording in the Work Instructions. If the import contains other non-counterfeit products, please continue to create the cases as usual without sending the notification as the ABF prefer to have the treatment of the whole consignment at once (do not send the 42F notification at this point for mixed imports).

For Compliance Officers: If you have an import of these products only, you can now record a decision point that references this critical decision, before sending a 42F notification in my name that has not had separate/tasked approval in CRM. If there is multiple products including products outside the remit of this decision point, you can use the 42F notification alongside the other delegate notifications.

Example running sheet entry for 42F notification:

This import is of a product that is a known counterfeit (Name of product) See:
Iversun-12 – Project 2828
Iverguard-12 – Project 2821

Iverhuman-12 - Project 2828
Ivetab-12 - Project 2582
Covimectin-12 - Project 2854
Iverheal-12 - Project 2853
Iverjohn-12 – Project 2951
Ivervic-12 – Project 2992
The COA is still valid. A routine compliance response is appropriate.
Approval has been given by s22 [redacted], Product and Import Compliance for forfeiture of goods via 42F notification, via Critical Decision on 24 March 2024 at: Issues and Decisions Register reference **D25-05** departing from our usual process of individual delegate approval. See issue and Decision Register for further information.
I am satisfied that on review, the import of (Name of product) is consistent with the product tested in Project #, and as such, is counterfeit. As Delegate approval has already been provided for this product, the 42F notification with delegate approval from s22 [redacted] has been provided to the ABF.

***Mixed imports**: If you have a mixed import, ie counterfeit ivermectin and hydroxychloroquine or other non-counterfeit medicines/TG's please record the decision point for the counterfeit ivermectin and provide a copy of the 42F notification at the end of the case so that the ABF have the treatment of all the products in the consignment in one fell swoop.*

***Be careful of the dosage:** Some of these 12mg products come in other strengths. The testing only applies to the 12mg product tested, not any 3mg, 6mg or other versions of the same product,*

This will be entered into the Issues and Decisions register at D25-05, and recorded in TRIM.

Regards,

s22 [redacted] *She/her)*
s22 [redacted] – Product Import Compliance and Triage
Regulatory Practice and Support Division | Health Products Regulation Group
Regulatory Compliance Branch
Therapeutic Goods Administration
Australian Government Department of Health and Aged Care
T: s22 [redacted] | M: s22 [redacted]
E: s22 [redacted] @health.gov.au Protected: s22 [redacted] @protected.health.gov.au
27 Scherger Drive, Canberra Airport, ACT 2609
TGA Building Level 2 North
PO Box 100, Woden ACT 2606, Australia

Office: Tuesday, Wednesday and Thursday
Remote: Monday and Friday
Making flexibility work - if you receive an email from me outside of normal business hours, please don't feel compelled to respond as I will often work at a time that suits me. Unless I reach out to you via phone or text, I'm not expecting you to read or reply until your normal business hours.
The Department of Health and Aged Care acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22
To:
Cc:
Subject: RC-036280 - Ivervid-12 [SEC=OFFICIAL]
Date: Thursday, 20 March 2025 3:01:25 PM
Attachments: image001.png

Good Afternoon

Please see the report relating to the laboratory analysis for the above investigation: D25-690325

Links to the Certificate of Analysis and photographs are located within the report.

If you have any questions about our findings, please contact me.

Regards,

s22 - Chemistry Section
Laboratories Branch

Medical Devices & Product Quality Division | Health Products Regulation Group
Australian Government Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
Location: Level 1, 1 Tindal Lane, Fairbairn, ACT
PO Box 100, Woden ACT 2606, Australia

Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Trade and Goods Operational Policy
Customs Compliance Branch
Australian Border Force
By email: tradeandgoodsoperationalpolicy@abf.gov.au

Dear Comptroller General,

Notification regarding application of the *Customs Act 1901* to the importation of counterfeit therapeutic goods

As a delegate of the Secretary, I am notifying you under subsection 42F of the *Therapeutic Goods Act 1989* (the Act) that the Secretary wishes the *Customs Act 1901* (Customs Act) to apply to importation/s of the following therapeutic goods for use in humans between 24 March 2025 and 30 June 2025:

- Iversun-12 branded ivermectin 12mg tablets
- Covimectin-12 branded ivermectin 12mg tablets
- Iverheal-12 branded ivermectin 12mg tablets
- Iverhuman-12 branded ivermectin 12mg tablets
- Ivetab-12 branded ivermectin 12mg tablets
- Iverguard-12 branded ivermectin 12mg tablets
- Iverjohn-12 branded ivermectin 12mg tablets
- Ivervid-12 branded ivermectin 12mg tablets

I am satisfied that these ivermectin products are counterfeit goods within the meaning of subsection 42E(2) of the Act, insofar as the label or presentation of the goods misrepresents the strength or size of any ingredient of the goods, being a false representation of a matter set out in subsection 42E(3) of the Act.

Evidence supporting my conclusion can be provided on request.

Accordingly, by virtue of this notification under subsection 42F(1) of the Act, the Customs Act has effect as if the goods included in the importation were goods described as forfeited to the Crown under section 229 of the Customs Act because they were prohibited imports within the meaning of that Act.

If you would like to discuss this matter further, please contact the Product and Import Compliance Section at s22@health.gov.au.

Yours sincerely

s22

s22
Delegate of the Secretary
Regulatory Compliance Branch
Therapeutic Goods Administration
25 March 2025
[This document is electronically signed]

Our reference:

Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Trade and Goods Operational Policy
Customs Compliance Branch
Australian Border Force
By email: tradeandgoodsoperationalpolicy@abf.gov.au

Dear Comptroller General,

Notification regarding application of the *Customs Act 1901* to the importation of counterfeit therapeutic goods

As a delegate of the Secretary, I am notifying you under subsection 42F of the *Therapeutic Goods Act 1989* (the Act) that the Secretary wishes the *Customs Act 1901* (Customs Act) to apply to importation/s of the following therapeutic goods for use in humans between 1 July 2025 and 1 October 2025:

- Iversun-12 branded ivermectin 12mg tablets
- Covimectin-12 branded ivermectin 12mg tablets
- Iverheal-12 branded ivermectin 12mg tablets
- Iverhuman-12 branded ivermectin 12mg tablets
- Ivetab-12 branded ivermectin 12mg tablets
- Iverguard-12 branded ivermectin 12mg tablets
- Iverjohn-12 branded ivermectin 12mg tablets
- Ivervid-12 branded ivermectin 12mg tablets

I am satisfied that these ivermectin products are counterfeit goods within the meaning of subsection 42E(2) of the Act, insofar as the label or presentation of the goods misrepresents the strength or size of any ingredient of the goods, being a false representation of a matter set out in subsection 42E(3) of the Act.

Evidence supporting my conclusion can be provided on request.

Accordingly, by virtue of this notification under subsection 42F(1) of the Act, the Customs Act has effect as if the goods included in the importation were goods described as forfeited to the Crown under section 229 of the Customs Act because they were prohibited imports within the meaning of that Act.

If you would like to discuss this matter further, please contact the Regulatory Compliance Section at s22@health.gov.au.

Yours sincerely

s22

s22
Delegate of the Secretary
Regulatory Compliance Branch
Therapeutic Goods Administration
1 July 2025
[This document is electronically signed]

Our reference: D25-2846555

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Trade and Goods Operational Policy
Customs Compliance Branch
Australian Border Force
Allara House, 48 Allara Street
Canberra ACT 2600

- Our Reference: **RC-036280**, Your reference: **GR-240084289**

Importation of Suspected Counterfeit Therapeutic Good/s

The Therapeutic Goods Administration (TGA) suspects that the goods being imported may be counterfeit goods within the meaning of subsection 42E(2) of the Act, insofar as a document or record relating to the goods or their manufacture represents that the strength or size of any ingredient of the goods, being a false representation of a matter set out in subsection 42E(3) of the Act.

The basis of this suspicion is that:

- TGA has previously tested the product and found it to contain less than the declared active pharmaceutical ingredient (API), being ivermectin, a Schedule 4 (Prescription Only) Medicine. However, the Certificate of Analysis has since expired, and the product requires re-testing to confirm the strength of the declared API.

As such, a sample of the following product/s is requested for the purpose of analysis by the TGA Laboratories.

20 tablets of Ivervid-12, containing ivermectin.

This sample can be transferred to the TGA addressed to:

s22 [redacted]
Regulatory Compliance Branch
Therapeutic Goods Administration
TGA Building Level 2 North
27 Scherger Drive
Canberra Airport, ACT 2609

On completion of testing by the TGA Laboratories, a Certificate of Analysis certifying that an Official Analyst appointed under Regulation 25 of the *Therapeutic Goods Regulations 1990* has examined and analysed a sample of therapeutic goods will be provided.

Should the goods be confirmed to be counterfeit, a delegate of the Secretary will also provide notification that under s42F of the Act that the Secretary wishes the Customs Act 1901 to apply to the goods, and that they are satisfied that the goods being imported are counterfeit goods within the meaning of subsection 42E(2) of the Act, insofar as the label or presentation of the goods represents that the presence or absence of any ingredient of the goods, being a false representation of a matter set out in subsection 42E(3) of the Act.

Then, that under subsection 42F(1) of the Act, that the Customs Act has effect as if the goods included in the importation were goods described as forfeited to the Crown under section 229 of the Customs Act because they were prohibited imports within the meaning of that Act.

After the goods have been forfeited to the Crown under section 229 of the Customs Act, we may request ABF provide the remainder of the goods to TGA as evidence in support of a prosecution.

If you would like to discuss this matter further, please contact the s22 at s22@health.gov.au.

Yours sincerely,

s22

s22
Delegate of the Secretary
Regulatory Compliance Branch
Therapeutic Goods Administration
14 November 2024
[This document has been digitally signed]

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Trade and Goods Operational Policy
Customs Compliance Branch
Australian Border Force
Allara House, 48 Allara Street
Canberra ACT 2600

- Our Reference: **RC-030392**, Your reference: **GR-240024818**

Importation of Suspected Counterfeit Therapeutic Good/s

The Therapeutic Goods Administration (TGA) suspects that the goods being imported may be counterfeit goods within the meaning of subsection 42E(2) of the Act, insofar as a document or record relating to the goods or their manufacture represents that the formulation, composition or design of the goods or any ingredient or component of them, being a false representation of a matter set out in subsection 42E(3) of the Act.

The basis of this suspicion is that:

- There are similarities with the advertising, product, packaging, and/or dosage form of a previously tested and confirmed counterfeit indicating that the good may have been reformulated in an attempt to avoid detection

As such, a sample of the following product/s is requested for the purpose of analysis by the TGA Laboratories.

- 20 tablets of Iverjohn-12, Ivermectin 12mg; including any packaging the tablets are contained in.

This sample can be transferred to the TGA addressed to:

s22 [redacted]
Regulatory Compliance Branch
Therapeutic Goods Administration
TGA Building Level 2 North
27 Scherger Drive
Canberra Airport, ACT 2609

On completion of testing by the TGA Laboratories, a Certificate of Analysis certifying that an Official Analyst appointed under Regulation 25 of the *Therapeutic Goods Regulations 1990* has examined and analysed a sample of therapeutic goods will be provided.

Should the goods be confirmed to be counterfeit, a delegate of the Secretary will also provide notification that under s42F of the Act that the Secretary wishes the Customs Act 1901 to apply to the goods, and that they are satisfied that the goods being imported are counterfeit goods within the meaning of subsection 42E(2) of the Act, insofar as the label or presentation of the goods represents that the presence or absence of any ingredient of the goods, being a false representation of a matter set out in subsection 42E(3) of the Act. Then, that under subsection 42F(1) of the Act, that the Customs Act has effect as if the goods included in the importation were goods described as forfeited

to the Crown under section 229 of the Customs Act because they were prohibited imports within the meaning of that Act.

After the goods have been forfeited to the Crown under section 229 of the Customs Act, we may request ABF provide the remainder of the goods to TGA as evidence in support of a prosecution.

If you would like to discuss this matter further, please contact the s22 at s22@health.gov.au.

Yours sincerely

s22

s22
Delegate of the Secretary
Regulatory Compliance Branch
Therapeutic Goods Administration

22 April 2024

[This document has been digitally signed]

From: s22
To:
Cc:
Subject: RE: FOR EL1 REVIEW - DRAFT Safety Alert for Iverjohn-12 & Ivervid-12 [SEC=OFFICIAL:Sensitive]
Date: Friday, 30 May 2025 9:18:00 AM
Attachments: image005.png
image006.png
image007.png
image008.png
image009.png
image010.gif
image011.png

We need a new safety alert, with these two on it. We can't add it to the November advisory.

Thanks.

From: s22 @health.gov.au>
Sent: Friday, 30 May 2025 8:19 AM
To: s22 @health.gov.au>
Cc: s22 @Health.gov.au>
Subject: FW: FOR EL1 REVIEW - DRAFT Safety Alert for Iverjohn-12 & Ivervid-12 [SEC=OFFICIAL:Sensitive]

Good morning s22

We currently have a safety advisory for other counterfeit ivermectin Continuing imports of counterfeit ivermectin | Therapeutic Goods Administration (TGA). Would you like the below two added to the list on this page.

I have cc'd s22 as part of the handover.

Kind regards,

s22

s22 *(She/ Her)*
s22 Regulatory Compliance Section
Regulatory Practice and Support Division | Health Products Regulation Group
Regulatory Compliance Branch

Therapeutic Goods Administration
Australian Government Department of Health, Disability and Ageing
T: s22
E: s22 @health.gov.au

27 Scherger Drive, Canberra Airport, ACT 2609
TGA Building Level 2 North

PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22 [redacted] @Health.gov.au>
Sent: Wednesday, 26 March 2025 9:44 AM
To: s22 [redacted] @health.gov.au>
Subject: FOR EL1 REVIEW - DRAFT Safety Alert for Iverjohn-12 & Ivervid-12 [SEC=OFFICIAL:Sensitive]

Good morning s22

Please find below information associated with the safety Alert I have drafted at D25-1258506, regarding Iverjohn-12 and Ivervid-12.

Please find below information in line with you email dated 27 November 2024, to which I have attached the reports for ease of reference.

Iverjohn-12	
Reference:	RC-030392
Lab Report:	D25-690301 (Project 2951)
Background:	• On 19/03/2024 the ABF detected an import of 200 x Iverjohn-12 tablets. • TGA issued an import to destruction s19b WL to the importer on 22 April 2024 • On 5 May 2024, s22 [redacted] issued a 56A certificate to ABf and EL2 Approved Sample request to ABF • On 27 September the sample was procured by s22 [redacted] • On 28 October 2024 s22 [redacted] submitted sample to TGAL for assessment • On 20 March 2025, results received indicating: ○ *'This sample would not meet the requirements of the USP as the content is below 90.0% of the labelled amount … The content of ivermectin in the sample was 83.3% of the labelled content.'*

	On 25 March 2025, s22 [redacted] submitted a report regarding the results to WHO GSM for review

Ivervid-12	
Reference:	RC-036280
Lab Report:	D25-690325 (Project 2992)
Background:	• On 13/08/2024 the ABF detected an import of 300 x ivervid-12 tablets and 100 x Dox-100 tablets. • On 25 September 2024, s22 [redacted] issued a s19b WL to the importer • 16 October 2024, no response heard from importer and s22 [redacted] made decision point to proceed with 56A on DOX-100 tablets, and sample for ivervid-12 • On 8 November 2024, s22 [redacted] took carriage of this matter. • On 22 November 2024, s22 [redacted] requested a sample of ivervid-12 and then issued a 56A for DOX-100 • On 17 December 2024 sample procured by s22 [redacted] • On 23 December 2024, s22 [redacted] recorded the sample being moved to TGAL for review • On 21 March 2025, results received indicating: ○ *'This sample would not meet the requirements of the USP or the IP as the content is below 90.0% of the labelled amount. The content of ivermectin in the sample was 84.4% of the labelled content.'* • On 25 March 2025, s22 [redacted] submitted a report regarding the results to WHO GSM for review • On 26 March 2025, s22 [redacted] took carriage of the matter again

Kind regards,

s22 [redacted]
Compliance Officer – Product and Import Compliance Section
Regulatory Compliance Branch

Regulatory Practice and Support Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 [redacted] | E: s22 [redacted] @health.gov.au

Location: Fairbairn
PO Box 100, Woden ACT 2606, Australia

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.

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Laboratory Report

LB Reference: Project 2951
RCB reference: RC-030392

Re: *Iverjohn-12 Ivermectin Tablets USP*

Background

On Wednesday, 23 October 2024, Laboratories Branch (LB) Chemistry received a Request for Analysis form from s22 [redacted] of the TGA Product Import Compliance Section (PICS).On Thursday, 24 October 2024 LB Chemistry received the following sample.

- One, clear, plastic, tamper-evident, security bag bearing seal number *'A340762827'*. This bag contained two, blister trays labelled as '*Iverjohn-12 Ivermectin Tablets USP'*. Batch number '*SLT061'* and expiry date '*11/2026'* were printed on the blister tray.

The sample was assigned TGA sample number **2410003582** upon receipt.

According to the request for analysis, PICS obtained the sample from Australian Border Force. It is suspected to contain less than the labelled content of ivermectin.

PICS has requested LB Chemistry to check the amount of ivermectin in the sample.

Examination and Analysis

The sample was visually examined, photographed[1] and analysed. A '*Certificate of Analysis'* for the sample (D25-1154762 refers) is provided with this report. The results of the examination and analysis of the sample are reviewed below.

A photograph of the sample is provided in **Appendix 1** of this report.

(i) Visual examination

The sample consisted of twenty, white, round, biconvex tablets, debossed with a break-line on one face. Ten tablets were contained in each labelled blister tray. The average tablet weight (based on 10 tablets) was 130.1 mg.

Labelling details for the blister trays included 'Manufactured by: *Johnlee Pharmaceuticals Pvt. Ltd.'* and indicated that each tablet contained 12 mg of Ivermectin.

[1] The photographs are located in TRIM container E24-481813 TRIM record D24-4535349.

(ii) Testing

Analysis was conducted on 10 individual tablets, tested separately.

Confirmation of the presence of ivermectin and its content in the sample was determined by analysing each tablet in accordance with the assay test outlined in the *USP*[2] *- Ivermectin Tablets* monograph.

Ivermectin was identified in the sample. The average content in the sample was 83.3% of the labelled amount, with the variation between the 10 tablets ranging from 77.1% to 89.9% of the label claim.

This sample would not meet the requirements of the USP as the content is below 90.0% of the labelled amount.

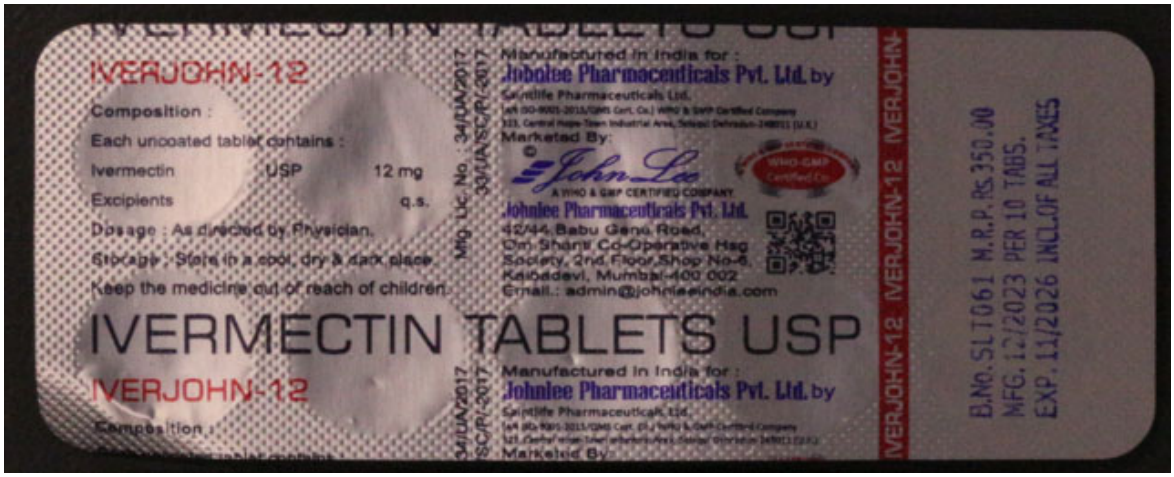
Conclusion

Ivermectin was identified in the sample of '*Iverjohn-12 Ivermectin Tablets USP*' (TGA sample number **2410003582**). The content of ivermectin in the sample was 83.3% of the labelled content.

Signed electronically by
s22
20/03/2025

Authorised by:
s22
s22, LB Chemistry

Appendix 1: Photograph of the sample



[2] United States Pharmacopeia

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Certificate of Analyst

A sample of therapeutic goods, bearing TGA sample number 2410003582 has been examined and analysed

The sample was submitted by s22 [redacted], Product Import Compliance Section (PIS), Regulatory Compliance Branch (RCB)
Results are applicable to the sample tested, as received by the TGA Laboratories Branch.

The goods were represented to be:

ARTG Number: N/A
Name: Iverjohn-12 Ivermectin 12mg
Sponsor: NOT AVAILABLE
Batch Number: SLT061
Expiry Date: 30-November-2026
Dosage Form: Tablet

TEST	RESULT	REQUIREMENT
TGA Seal Number	A340762827	
Sample Appearance		
	White, round, biconvex tablets, debossed with a break-line on one face. The average tablet weight (based on 10 tablets) was 130.1 mg. The tablets were contained in labelled, aluminium blister trays (each containing 10 tablets). The blister trays were presented in a sealed 'Tamper Evident Security Bag'	
Content of Ivermectin by UPLC (USP)	83.3 %	90.0 to 110.0 %
Identification of Ivermectin by UPLC (USP)	Present	Present
Uniformity of dosage units - content uniformity	Acceptance Value (AV) = 24.8 (83.8, 87.4, 85.4, 82.4, 81.7, 79.9, 79.0, 86.1, 89.9, 77.1 %LC)	AV = 15.0 or less

Abbreviations: USP = United States Pharmacopeia; UPLC = ultra performance liquid chromatography

This Certificate has been signed and issued electronically by the nominated analyst

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Email: info@tga.gov.au https://www.tga.gov.au

TGA Health Safety Regulation

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Office use only

Request for Laboratory Analysis

Requestor Details

Name / Phone	s22 [redacted]
Title	s22 [redacted]
Section / Branch	Product and Import Compliance
Email for Results Distribution	s22 [redacted]@Health.gov.au

Request Information

Request Date	17/12/2024
Reference & TRIM No	RC-036280 D24-5319303
Request to	Chemistry Section

Request and Sample Information

Background Information

The Product and Import Compliance Section (PICS) received a referral, from Australian Border Force (ABF) in relation to Ivervid 12 Ivermectin tablets.

The product is not registered in the Australian Registered of Therapeutic Goods (ARTG).

PICS have particular concerns as to whether the product contains the labelled concentration/dosage of API ivermectin (12mg). This is because an imported product was subject to TGA Laboratory testing in 2022 and found to contain less than the declared API (Project 2647).

Sample Information

Total Number of Samples/Products Provided to Laboratories Branch	20 tablets

Please complete Appendix 1 - Sample Details

Storage Conditions	PICS cannot verify how it was stored at the ABF – the ABF did not refer the product as being imported in refrigerated or cold chain conditions and it appears as if it was mailed in a standard satchel. It has been stored in ambient temperature since delivery to the TGA.

Were the samples requested:

- Under Subregulation 28(5)(h) of the *Therapeutic Goods Act*? ☐ Yes ☒ No
- Under Subregulation 41FN(2) of the *Therapeutic Goods Act*? ☐ Yes ☒ No

or

- Taken by an Authorised Officer/Person under the *Therapeutic Goods Act*? ☐ Yes ☒ No

Note: Samples requested under s28(5)(h) or s41FN(2) must be received by delegate under Subregulation 26(A) of the *Therapeutic Goods Regulations.* Please discuss the requirements with the testing area

Testing Requested

Confirmation of 12mg Ivermectin within each tablet.

Testing Timeframes

	Medicines (including vaccines and biological medicines)	Medical Devices
☐ **Urgent**	*Samples associated with a serious adverse event that has occurred and has the potential to recur. A serious adverse event is any untoward medical occurrence that, at any dose, results in the following conditions:* • death; • a life-threatening event (Note: The term 'life-threatening' in the definition of 'serious' refers to an event/reaction in which the patient was at risk of death at the time of the event/reaction; it does not refer to an event/ reaction which hypothetically might have caused death if it were more severe); • inpatient hospitalisation or results in prolongation of existing hospitalisation; • persistent or significant disability/incapacity; • a congenital anomaly/birth defect; or • a medically important event or reaction.	*Samples associated with a serious adverse event that has occurred and has the potential to recur. A serious adverse event is an event that led to the following conditions:* • death • a serious injury or serious deterioration to a patient, user or other person, including: • a life-threatening illness or injury • permanent impairment of a body function • permanent damage to a body structure; or • a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure
☐ **Priority**	Intelligence indicates that laboratory investigation is necessary to prevent a serious adverse event.	
☒ **Routine**	All other samples	
☐ **Request**	Please provide details of the need for an accelerated timeframe, including the deadline date and reason Example: Court proceedings scheduled for 29th February 2024, results will be required by 15th January 2024 to allow preparation of the case. Click or tap here to enter text.	

Target timeframes are **20** work days for Urgent samples, **40** work days for Priority samples, and **50** work days for Routine samples. Microbiology timeframes may exceed 20 work days due to incubation periods.

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Fill in the table most relevant to the sample/s requiring laboratory testing.

Devices and registered/listed products

ARTG Number	Product Name as per ARTG* (include dosage form)	Sponsor /Manufacturer	Batch and/or Serial Number	Expiry Date	Evidence Tag Number	Intended Purpose (Medical Devices only)	Device Class	LIMS Number (LB Use Only)

* if the ARTG name differs from the name on the label, include both names here and indicate which should appear on the Certificate of Analysis once testing is complete.

Unregistered and seized products

CRM Exhibit number	Evidence Bag number	Product Name	Batch Number	Expiry Date	Comments or Additional Information	LIMS Number (LB Use Only)
RC-PI-02757	A260653525	20 x tablets of Ivervid 12 Ivermectin	TI-1230001	02/2027		2412004166

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Laboratory Report

LB Reference: Project 2992
RCB reference: RC-036280

Re: *Ivervid 12 Ivermectin Tablets IP 12 mg*

Background

On Wednesday, 18 December 2024, Laboratories Branch (LB) Chemistry received a Request for Analysis form from s22 of the TGA Product Import Compliance Section (PICS).On Monday, 23 December 2024 LB Chemistry received the following sample.

- One, clear, plastic, tamper-evident, security bag bearing seal number *'A260653525'*. This bag contained two, blister trays labelled as '*Ivervid 12 Ivermectin Tablets IP 12 mg'*. Batch number '*TI-1230001'* and expiry date '*04/2027'* were also included on the blister tray.

The sample was assigned TGA sample number **2412004166** upon receipt.

According to the request for analysis, PICS obtained the sample from Australian Border Force. It is suspected to contain less than the labelled content of ivermectin.

PICS has requested LB Chemistry to investigate the amount of ivermectin in the sample.

Examination and Analysis

The sample was visually examined, photographed[1] and analysed. A '*Certificate of Analysis'* for the sample (D25-1159710 refers) is provided with this report. The results of the examination and analysis of the sample are reviewed below.

A photograph of the sample is provided in **Appendix 1** of this report.

(i) Visual examination

The sample consisted of twenty, white, round, biconvex tablets, debossed with a break-line on one face. Ten tablets were contained in each labelled blister tray. The average tablet weight (based on 10 tablets) was 109.3 mg.

Labelling details for the blister trays included 'Manufactured by: *Fortune Healthcare Product Pvt. Ltd.'* and indicated that each tablet contained 12 mg of Ivermectin.

[1] The photographs are located in TRIM container E24-585415 TRIM record D24-5425477.

(ii) Testing

Analysis was conducted on 10 individual tablets, tested separately.

Confirmation of the presence of ivermectin and its content in the sample was determined by analysing each tablet in accordance with the assay test outlined in the *USP*[2] *- Ivermectin Tablets* monograph.

Ivermectin was identified in the sample. The average content in the sample was 84.4% of the labelled content, with the variation between the 10 tablets ranging from 81.8% to 88.1%.

This sample would not meet the requirements of the USP or the IP[3] as the content is below 90.0% of the labelled amount.

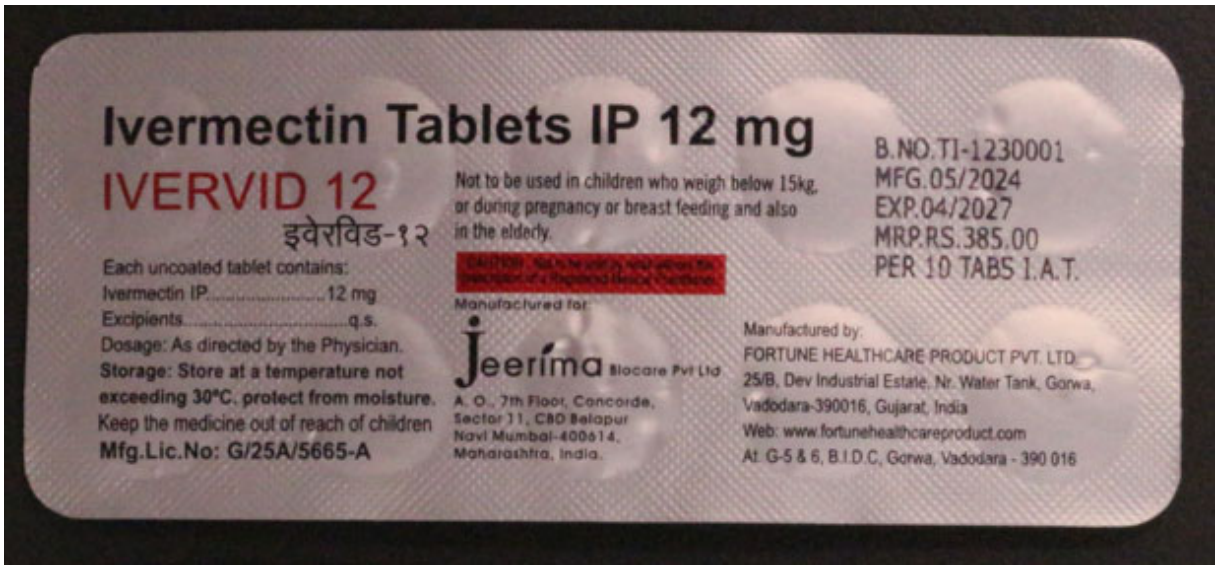
Conclusion

Ivermectin was identified in the sample of '*Ivervid 12 Ivermectin Tablets IP 12 mg'* (TGA sample number **2412004166**). The content of ivermectin in the sample was 84.4% of the labelled content.

Signed electronically by
s22
20/03/2025

Authorised by:
s22
s22, LB Chemistry

Appendix 1: Photograph of the sample



[2] United States Pharmacopeia
[3] Indian Pharmacopoeia

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Certificate of Analysis

A sample of therapeutic goods, bearing TGA sample number 2412004166 has been examined and analysed

The sample was submitted by s22 [redacted] for s22 [redacted]

Results are applicable to the sample tested, as received by the TGA Laboratories Branch.

The goods were represented to be:

ARTG Number: N/A

Name: Ivervid 12 Ivermectin Tablets

Sponsor: NOT AVAILABLE

Batch Number: TI-1230001

Expiry Date: 30-April-2027

Dosage Form: Tablet

TEST	RESULT	REQUIREMENT
TGA Seal Number	A260653525	
Sample Appearance		
White, round, biconvex tablets, debossed with a break-line on one face. The average tablet weight (based on 10 tablets) was 109.3 mg. The tablets were contained in labelled, aluminium blister trays (10 blister trays each containing 10 tablets). The blister trays were presented in a sealed 'Tamper Evident Security Bag'		
Content of Ivermectin by UPLC (USP)	84.4 %	90.0 to 110.0 %
Identification of Ivermectin by UPLC (USP)	Present	Present
Uniformity of dosage units - content uniformity	Acceptance Value (AV) = 19.4 (85.0, 88.1, 82.2, 85.2, 81.8, 84.8, 82.3, 85.8, 86.9, 82.2 %LC)	AV = 15.0 or less

Abbreviations: UPLC = ultra performance liquid chromatography; USP = United States Pharmacopeia

This Certificate has been signed and issued electronically by the nominated analyst

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TGA Health Safety Regulation