Australian Government
Department of Health
Therapeutic Goods Administration

GMP Inspection Trends for Non-Sterile Registered Medicines

Common deficiencies and FAQs from the GMP inbox

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TGA Health Safety Regulation

Australian Government
Department of Health
Therapeutic Goods Administration

Overview

- TGA GMP Inspection trends
- Data integrity & computerised systems
- FAQ – Medicinal cannabis

Common inspection deficiencies

- Poor cross-contamination controls
- Insufficient evidence to support practical training of personnel
- Inadequate facility and equipment qualification, and process validation

Common inspection deficiencies

Poor management of quality incidents

- Customer complaints, deviations & OOS incompletely investigated and documented
- Analysis of likely root cause not systematically applied during investigation of deviations & suspected product defects
- Quality Risk Management principles not used in the assessment & control of quality incidents

Common inspection deficiencies

Control of computerised systems

- No up-to-date listing of computerised systems and their GMP functionality
- Inadequate user access control
- Poor control of data on standalone systems
- Issues with audit trails
- Assessment & control of third party suppliers of cloud services
- Computer systems not validated for intended use

Control of computerised systems

Listing of computerised systems and their GMP functionality

- No consolidated listing available
- Missing information e.g. PLC controlled packaging equipment, simple testing instruments such as auto titrators, pH meters.
- Interfaces with other systems or processes not documented

Control of computerised systems

User access control

- Lack of individual user logins for systems
- Hierarchical access levels not implemented
- Inappropriate use of Administrator login

Control of computerised systems

Control of standalone systems

- Back up of electronic data poorly administered
- Unique user logins no implemented
- Time / date on computer can be modified by user
- Data can be deleted from hard drives without detection

Control of computerised systems

Audit trail reviews

- Audit trails not available for all systems
- Audit trail not regularly reviewed
- Review requirements not formalised in procedures
- Orphan data not included in analysis
- Reconciliation of electronic data with associated logbooks not considered

Control of computerised systems

Third party suppliers of cloud services

- Supplier assessment of cloud service providers not conducted
- No formal agreement in place between the manufacturer and cloud service provider outlining GMP responsibilities
- No risk assessment conducted to identify risk associated with using third parties who are creating, processing or storing regulated data

Control of computerised systems

Computerised system verification for intended use

- No URS available for newly installed computerized systems
- Documentation supplied with commercial off-the-shelf products not reviewed to ensure user requirements are fulfilled
- Validation reports for critical system contained inadequate system descriptions:
  - data flows and interfaces with other systems or processes
  - hardware and software pre-requisites
  - security measures

Medicinal Cannabis FAQs

Therapeutic Goods Act 1989

Part 3–3 Manufacturing of therapeutic goods

Section 35 - Criminal offences relating to manufacturing therapeutic goods

(1) A person commits an offence if:

(a) the person, at premises in Australia, **carries out a step in the manufacture of therapeutic goods** (other than goods exempt under section 18A or 32CB); and

(b) **the goods are for supply for use in humans**; and

(c) **none of the following applies**:

(i) **the goods are exempt goods**;

(ii) **the person is an exempt person** in relation to the manufacture of the goods;

(iii) **the person is the holder of a licence that is in force that authorises the carrying out of that step in relation to the goods at those premises**

Therapeutic Goods Act 1989 - Definitions

Manufacture, in relation to therapeutic goods that are not medical devices, means:

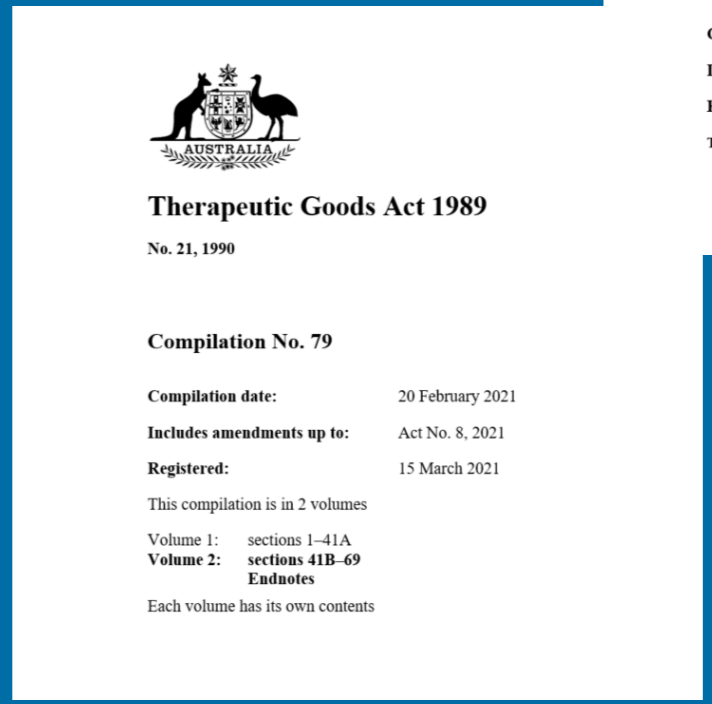
(a) to produce the goods; or

(b) **to engage in any part of the process of producing the goods or of bringing the goods to their final state**, including engaging in the processing, assembling, packaging, labelling, storage, sterilising, testing or releasing for supply of the goods or of any component or ingredient of the goods as part of that process.

Therapeutic Goods Act 1989, Part 3–3, Section 35

Schedule 7 - Therapeutic goods exempt from the operation of Part 3-3 of the Act

Schedule 8 - Persons exempt from the operation of Part 3-3 of the Act



AUSTRALIA

Therapeutic Goods Act 1989

No. 21, 1990

Compilation No. 79

Compilation date:	20 February 2021
Includes amendments up to:	Act No. 8, 2021
Registered:	15 March 2021

This compilation is in 2 volumes

Volume 1: sections 1–41A
Volume 2: sections 41B–69
Endnotes

Each volume has its own contents

AUSTRALIA

Therapeutic Goods Regulations 1990

Statutory Rules No. 394, 1990

made under the

Therapeutic Goods Act 1989

Compilation No. 98

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This compilation includes commenced amendments made by F2019L01660

Therapeutic Goods Act 1989, Part 3–3, Section 35

Schedule 7 - Therapeutic goods exempt from the operation of Part 3-3 of the Act

Item 1: goods prepared for the initial experimental studies in human volunteers

Item 2: ingredients, except water, used in the manufacture of therapeutic goods where the ingredients:

(a) **do not have a therapeutic action**; or

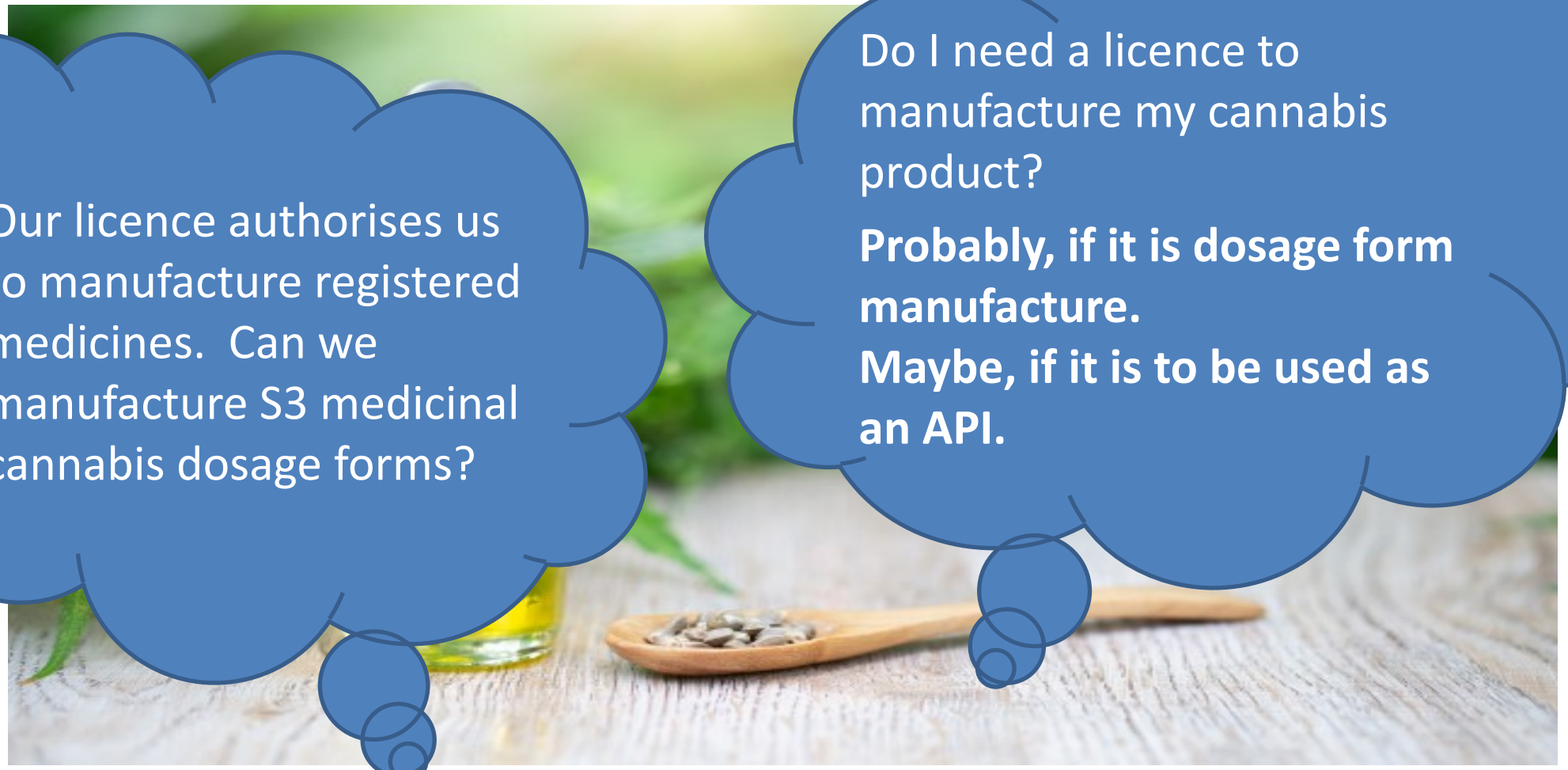
(b) **are herbs**, bulk hamamelis water, **or oils extracted from herbs, the sole therapeutic use of which is as starting materials for use by licensed manufacturers**

Therapeutic Goods Act 1989, Part 3–3, Section 35

Schedule 8 - Persons exempt from the operation of Part 3-3 of the Act

- Item 1: medical practitioners, dentists and other health care workers registered under a law of a State or Territory
- Item 2: pharmacists
- Item 4: herbalists, nutritionists, naturopaths, practitioners of traditional Chinese medicine or homoeopathic practitioners engaged in the manufacture of any herbal, homoeopathic or nutritional supplement preparation
- Item 5: a person who applies supplementary labelling that contains only a name and address, or the registration or listing number of goods, to a manufactured product
- Item 6: a person who re-labels a product to comply with the labelling requirements of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSMP)

Medicinal Cannabis FAQs



Our licence authorises us to manufacture registered medicines. Can we manufacture S3 medicinal cannabis dosage forms?

Do I need a licence to manufacture my cannabis product?

Probably, if it is dosage form manufacture.
Maybe, if it is to be used as an API.

Supply of medicinal cannabis products

The *Therapeutic Goods Act* provides that a person who is the sponsor of therapeutic goods must not import, export, manufacture or supply those goods unless the goods are:

- entered on the Register as listed or registered goods
- supplied under one of the following approved alternative pathways:

a. the authorised prescriber scheme

b. the Special Access Scheme B

c. a clinical trial

Supply of medicinal cannabis products

CBD products have been down-scheduled to S3

Schedule 3 – CANNABIDIOL in oral, oromucosal and sublingual preparations **included in the Australian Register of Therapeutic Goods** when CBD at >98%

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Oral Liquid	Registered Therapeutic Good	Finished Product Manufacture

Supply of medicinal cannabis products

Supply under one of the approved alternative pathways

- authorised prescriber scheme / Special Access Scheme B
- clinical trial

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Oral Liquid	Not Applicable	Finished Product Manufacture
Medicine manufacture	Non Sterile	Oral Liquid	Therapeutic Goods for Clinical Trials	Finished Product Manufacture
Medicine manufacture	Non Sterile	Oral Liquid	Registered Therapeutic Good	Finished Product Manufacture

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