Queensland Health Departmental Standard

Compounding – version 1

27 September 2021

Queensland Government

Queensland Health Departmental Standard
Compounding – version 1

Published by the State of Queensland (Queensland Health), September 2021

For more information contact:

Chief Medical Officer and Healthcare Regulation Branch, Prevention Division, Queensland Health, GPO Box 48, Brisbane QLD 4001, email HLIU@health.qld.gov.au

Version control

Version	Replaces version	Date approved	Commencement date
1	NA	12 August 2021	27 September 2021

Contents

Preface

The *Medicines and Poisons Act 2019* (the Act) establishes a contemporary framework for the regulation of medicines, poisons, pesticides and other prohibited substances in Queensland. This framework will impact a broad range of persons.

This framework includes three regulations (the Regulations):

- Medicines and Poisons (Medicines) Regulation 2021;
- Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021; and
- Medicines and Poisons (Pest Management Activities) Regulation 2021.

The Act authorises the Chief Executive of Queensland Health to make departmental standards in relation to matters regulated under the Act (section 233, Part 4, Chapter 7 of the Act).

A departmental standard outlines the mandatory expectations and specific requirements needed to ensure regulatory compliance with the Act and Regulations.

This standard (Compounding Standard) has been made by the Director-General, Queensland Health in accordance with section 233 of the Act.

Object

The purpose of this standard is to define necessary infrastructure, in terms of the compounding environment, equipment and systems requirements, to ensure that compounded medicines are safe, efficacious and of a high quality.

Scope

All persons engaged in compounding are responsible for ensuring that quality is built into the compounding of medicines. Pharmacists are authorised to compound medicines for human use in the *Medicines and Poisons (Medicines) Regulation 2021* ('Medicines Regulation').

Section 47 of the Medicines Regulation requires an authorised person who compounds a medicine to ensure that medicines are compounded in accordance with this Standard. Failure to comply with this Standard may result in harm to patients due to the administration of an unsafe or inappropriate medicine.

Compounded medicines also have to meet quality standards determined by orders made by the relevant Minister under section 10 of the *Therapeutic Goods Act 1989 (Cth)*. These can be Ministerial orders establishing a standard (such as Therapeutic Goods Orders) or by reference to default standards (for example, monographs in the British Pharmacopoeia or the United States Pharmacopeia-National Formulary). It is the responsibility of the authorised person engaged in compounding to ensure that compounded medicines comply with all relevant standards and guidelines.

In addition, pharmacists must refer to current guidelines published by the Pharmacy Board of Australia and the current version of the Australian Pharmaceutical Formulary and Handbook for other requirements with respect to compounding medicines.

Section 1 - Place

Outcome	Minimum requirements
The place used for compounding minimises the risk of particulate or microbial contamination of compounded medicines, in a way appropriate to the type of compounding being undertaken.	Compounding is undertaken in a place that: a. has an area that is dedicated for the purpose of compounding; b. has working surfaces that are in good condition, hygienic, and covered with impervious washable materials; c. has a sink supplied with running water; d. is adequately enclosed, ventilated, painted and lit; and e. is kept clean and free from anything able to contaminate a medicine.

Section 2 – Equipment

Outcome	Minimum requirements
The equipment used for compounding is dedicated to compounding and is in good working order.	The equipment is: a. appropriate for the accuracy requirements of the quantities being measured; b. cleaned before and after product preparation; c. maintained and calibrated regularly, according to a documented procedure; d. stored in a manner that protects it from damage and contamination; and e. clearly labelled and stored separately from other equipment if it is used to compound preparations that contain potentially hazardous ingredients. Sterile compounding is undertaken: a. within cleanrooms that meet relevant Australian Standards in force from time to time and using laminar flow cabinets and laminar flow workbenches that meet relevant Australian Standards in force from time to time; or b. in a pharmaceutical isolator that meets relevant Australian Standards in force from time to time.

Section 3 – Raw materials storage

Outcome	Minimum requirements
The conditions under which raw materials are stored minimise the risk of contamination and maintains their quality.	Raw materials are stored in accordance with the manufacturers' recommended conditions. Containers and packaging used to store raw materials can maintain the quality and stability of the raw materials including, for example, the use of light-resistant and moisture-proof containers and packaging where necessary.
The conditions under which raw materials that are hazardous substances are stored minimise the risk of harm to the public and employees.	Raw materials that are hazardous substances are stored in enclosed containers that prevent the chemical contaminating other raw materials. Cytotoxic substances have cytotoxic warning labels on the outer packaging.

Section 4 – Standard operating procedures

Outcome	Minimum requirements
Standard operating procedures support the consistent and safe supply of high-quality compounded medicines.	Standard operating procedures relevant to the compounding being undertaken are established, implemented and maintained, including procedures for: a. the training, validating and monitoring of staff involved in compounding; b. the operation and cleaning of the area used for compounding; c. maintenance of equipment including a planned maintenance schedule; d. dealing with complaints and recalls of compounded products including tracking and retrieving any dispensed compounded products; e. spillage, storage and disposal of waste; f. packaging, labelling, handling and storage of products; and g. quality assurance.

Section 5 – Documentation and record keeping

Outcome	Minimum requirements
There are written records demonstrating compliance with standard operating procedures.	Records/logs are made, and are available for inspection, that include: a. a record of staff training; b. a log of cleaning of the area used for compounding; c. a log of equipment calibration and maintenance; d. a register of complaints and recalls; and e. a register listing each hazardous substance used and a material safety data sheet for each ingredient.
There is a written record about each compounded medicine.	A signed and dated record is made for each medicine that is compounded that includes: a. the risk assessment undertaken prior to compounding the medicine; and b. the approved name of the ingredients, the formula (and its source including edition), the procedure, and the strength/amount of any preservatives used; and c. the source, batch number and expiry date of ingredients used; and d. if water is an ingredient, the type of water used, its date of preparation or opening, and the manufacturer's batch number (where applicable); and e. any considerations about the stability of the medicine, methodologies, notes, and calculations, with references where appropriate; and f. any ancillary labels or additional instructions used.

Glossary

Term	Meaning
approved name	The name approved for use by the Therapeutic Goods Administration See the Australian Approved Names List for Therapeutic Substances, as in force from time to time, published by the Therapeutic Goods Administration and available at https://www.ebs.tga.gov.au/
Australian Standard	A standard developed under the Australian Standard name.
compound and/or compounding	As defined in Schedule 22 of the Medicines Regulation.
cytotoxic substance	A medicine which causes the death of certain cells, and is used to treat conditions such as cancer and rheumatoid arthritis.
hazardous substance	A substance that poses an occupational health and safety hazard (such as cytotoxic substances and hormones).
pharmacist	As defined in Schedule 22 of the Medicines Regulation

A term used in this Standard that is defined in the Act or the Medicines Regulation, and is not referred to in this glossary, has the meaning stated in the Act or Medicines Regulation.