

# PHARMACY PREMISES COMMITTEE OF THE NORTHERN TERRITORY

## PS12 STANDARD FOR COMPOUNDING LABORATORIES IN PHARMACIES AND PROFESSIONAL SERVICES PREMISES

*Version 1*

**PHARMACY PREMISES COMMITTEE OF THE NORTHERN TERRITORY****PS12 Standard for Compounding Laboratories in Pharmacies  
and Professional Services Premises**

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# PHARMACY PREMISES COMMITTEE OF THE NORTHERN TERRITORY

## PS12 Standard for Compounding Laboratories in Pharmacies and Professional Services Premises

### 1. GENERAL INFORMATION

**1.1** Pursuant to the *Health Practitioners Act (HPA)*, Schedule 7, Clause 4 the Pharmacy Premises Committee (Committee) prescribes that all pharmacies containing a compounding laboratory must comply with the following standard.

**1.2** Compounding Laboratories found to be in compliance with the following standard will be issued a Certificate of Compliance under the following conditions:

- effective for one year;
- valid only for the address listed
- not transferrable from the current ownership structure; and
- not valid if the laboratory and/or premises undergoes major retrofitting.

### 2. OVERVIEW

The compounding laboratory must be an enclosed area with sufficient space for the safe provision of compounding therapeutic products. The laboratory must:

- maintain adequate records for the production of pharmaceutical products for human and veterinary use;
- provide adequate safeguards to ensure the integrity of the final product;
- provide the necessary lighting, temperature and humidity control applicable for the products being produced; and
- protect consumer privacy.

### 3. DEFINITIONS

#### 3.1 Compounding Laboratory

Compounding laboratories in pharmacies and professional services premises can be defined as:

- a dedicated space (laboratory) separated from other parts of the premises by floor to ceiling walls or partitions and have at least one doorway.

The laboratory must have:

- a floor that is impervious;
- walls, benchtops, shelves and ceiling that is washable;
- all equipment as is required to carry out the required compounding activities; and
- sufficient area to undertake compounding of medicines in a safe, secure manner.

#### 3.2 Compounding and manufacture

The *Therapeutic Goods Act 1989 (Cth)* provides the legal frame work for the import, export, manufacture and supply of therapeutic goods in Australia. Therapeutic goods are required to be entered onto the Australian Register of Therapeutic Goods (ARTG).

The manufacture of medicines must be in compliance the *Guide to Good Manufacturing Practice for Medicinal Products* and take place in premises approved by the Therapeutic Goods Administration (TGA).

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Exemptions exist for pharmacists in relation to the compounding of medicines for human use. These are:

- ARTG – compounded medicines are not required to be entered on to the ARTG prior to supply providing they are extemporaneously compounded for a particular person; and
- Manufacturing of medicines – a license is not required from the TGA providing the pharmacist is practising in a pharmacy which is open to the public or on the premises of a private hospital.

Note: Professional Services Premises containing a compounding laboratory may only supply compounded medicines to the pharmacy to which it is affiliated in order to be deemed to be working within the objects of the TGA.

#### 3.3 Veterinary Compounding

Compounding laboratories undertaking compounding of medicines for veterinary use must comply with the *Agricultural and Veterinary Chemicals Code (AgVet Code)*. The AgVet code authorises a veterinary surgeon to instruct a pharmacist to compound a medicine for use in an animal. The instruction must be in the form of a written instruction (a prescription or requisition order) and satisfy the requirements of the Medicines Poisons and Therapeutic Goods Act and accompanying Regulations.

The Australian Veterinary Association (AVA) has produced a guideline for the preparation and use of compounded pharmaceuticals in the veterinary industry. Pharmacists undertaking veterinary compounding are urged to familiarise themselves with this guideline.

#### 3.4 Simple Compounding

*‘The preparation and supply of a single ‘unit of issue’ of a therapeutic product intended for use by a specific person in response to an identified need’ – PBA, March 2015*

#### 3.5 Complex Compounding

*‘The preparation and supply of a single ‘unit of issue’ of a therapeutic product that is intended for immediate use by a specific patient and that requires or involves specific competencies, equipment, processes or facilities. Examples include sterile products and preparations containing ingredients which pose an occupational health and safety hazard such as cytotoxic agents or hormones, monoclonal antibodies, micro-dose single unit dosage forms containing less than 25mg of active ingredient’ – PBA, March 2015*

## 4. LABORATORY ACCESS AND PERSONAL PROTECTIVE EQUIPMENT

The laboratory must be restricted to persons who are trained or be under the supervision of suitably qualified persons. Before entering the compounding laboratory Personal Protective Equipment (PPE) must be worn. The PPE must be appropriate to the activities undertaken and the chemicals utilised either directly or indirectly.

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## **5. STAFF AND TRAINING**

All activities undertaken in the compounding laboratory need to be assessed on a risk analysis. The pharmacist-in-charge has the responsibility to make sure all staff employed to work in the compounding laboratory are appropriately trained.

The health and wellbeing of the staff employed to work on the compounding laboratory is also the responsibility of the pharmacist-in-charge.

Records of training and health assessments of staff dealing with high risk raw materials must be kept for all staff working in the compounding laboratory. These records must be produced if requested by authorised officers.

### **5.1 Pharmacists**

Pharmacists undertaking simple compounding activities should have the competencies to take on these activities. All pharmacists engaging in complex compounding are required to undertake formal training that is appropriate. The Pharmacy Board of Australia lists these competencies as:

- Compounding conventions and principles including chemical competencies;
- Utilisation of specialised information sources to identify suitable formulations;
- Safe handling and waste disposal; and
- Pharmacotherapeutic and pharmacokinetic considerations.

It is expected that pharmacists maintain these competencies as part of their professional development.

### **5.2 Dispensary Assistants, Dispensary Technicians and Interns**

Staff assisting the pharmacist such as assistants, technicians and interns must be suitably trained in order to undertake the activities required. All training must be documented and relevant to the compounding activity.

All activities in the compounding laboratory must be under the direct supervision of the pharmacist on duty. The supervising pharmacist must also be proficient in the competencies and techniques that the assistant is performing.

## **6. QUALITY AND STABILITY**

Occupational health and safety standards must be adhered to for all personnel working within the compounding laboratory. Risks associated with any compounding process must be documented and noted by all persons associated with the compounding laboratory.

### **6.1 Raw Materials and Quality Standards**

Raw materials must be obtained from reputable sources and be of a recognised standard. Examples include;

- Australian Pharmaceutical Formulary (APF);
- British Pharmacopeia (BP);
- United States Pharmacopeia (USP); and
- European Pharmacopeia.

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When raw materials can only be purchased from other sources – quarantining of these raw materials must be undertaken and testing of individual batches carried out. Additional guidance can be found in the Australian Pharmaceutical Formulary and Handbook.

Medicines compounded within compounding laboratories are not exempted from meeting prescribed standards listed in the Therapeutic Goods Act. These prescribed standards include standards for microbiology of non-sterile medicines and sterility testing of sterile compounded medicines. It is the responsibility of the pharmacist-in-charge to ensure the compounded medicines comply with all relevant standards.

#### 6.2 Formulary Documentation

All preparations compounded in the compounding laboratory must be documented. Documentation includes:

- stability data and efficacy data of all raw materials;
- formulary;
- stability of the final product; and
- a recommended shelf life.

If the product utilises Schedule 8 materials additional documentation of the use of these materials must be entered into a Schedule 8 register that is compliant with the Medicines Poisons and Therapeutic Goods Act. If the final product is a Schedule 8 medicine then additional registers must be kept.

## 7. EQUIPMENT

All equipment utilised in the compounding laboratory is expected to comply with Australian Standards. It should be relevant for the activities undertaken and be of a size that is applicable to the amount of medicines compounded.

Cleaning must be documented and logs kept for all equipment.

Maintenance must also be carried out at regular intervals and records must be kept of these activities. Included in these maintenance records is a record of perishable equipment (including batch numbers in case of a recall) used by the equipment. An example of this is High efficiency particulate air (HEPA) filters in powder containment units.

## 8. COMPOUNDING OF STERILE MEDICINES

The production sterile pharmaceuticals in compounding laboratories must only be undertaken if:

- the compounding laboratory and equipment meet applicable Australian Standards;
  - Compounding laboratories may be required to have their equipment tested and validated.
- equipment used in the production of sterile medicines is operated in accordance with the manufacturers specifications and the performance is documented and validated;
- all procedures are documented, reproducible and sourced from suitable resources; and
- suitable training and education is undertaken by all staff involved.

## 9. LIGHTING

All working areas used for the selection, preparation and supply of medicines must have adequate lighting in the range of 320 to 400 Lux.

Undue exposure of medicines to direct sunlight, or ultraviolet light, must be prevented.

## 10. TEMPERATURE CONTROL

The compounding laboratory must have the facility to ensure that recommended storage conditions for medicines are maintained at all times. For room temperature stable medicines, temperatures must not exceed 25°C. Where 24 hour temperature control is not possible, the laboratory must have a documented process to monitor and evaluate temperatures to ensure stock viability. This document may be contained in the pharmacy or the professional services premises.

The use of data loggers or minimum/maximum recording thermometers with appropriate documentation, are considered acceptable methods of monitoring temperatures.

Appropriate policies and procedures must be in place to ensure the integrity of all compounded and raw materials.

Consideration must also be given to the safety of all staff in the event of a power outage during a compounding process.

## 11. SCHEDULE 8 SAFE

Appropriate storage of Schedule 8 materials (raw or compounded) in a pharmacy or professional services premises must be accordance with the Code of Practice for the Transport and Storage of Schedule 8 Substances.

All Schedule 8 safes must be of sufficient size for the needs of the individual premises.

Consideration should be given to a separate Schedule 8 safe for raw and compounded products.

## 12. REFRIGERATOR

Temperature sensitive raw materials and medicines must be stored in such a manner as to protect the integrity safety and efficacy of the product. The pharmacy and professional services premises must have at least one refrigerator. Consideration should also be given to product placement within the refrigerator to prevent any possible contamination of raw and compounded medicines. It is recommended a separate refrigerator be used for raw and compounded products. All refrigerators used for the storage of raw and compounded products must comply with National Vaccine Storage Guidelines (*Strive for 5*) and dedicated to the storage of pharmaceutical products.

### 13. SINK ACCESS

All compounding laboratories must have at least one sink or have access to a sink for the cleaning of equipment.

A separate sink is also required for hand hygiene but may be located outside the laboratory. If the sink for hand hygiene is located outside of the laboratory, access to hand sanitising solution/gel must be available for use in the laboratory.

### 14. HYGIENE AND PEST CONTROL

The laboratory must be constructed in a manner to restrict the build-up of particles and debris. All fittings and fixtures must be kept clean and tidy with cleaning logs mandated.

All cleaning equipment must be maintained to support hygiene and infection control.

The laboratory must also be constructed and maintained to restrict entry of rodents, vermin and other pests. Animals including pets are strictly prohibited in the laboratory even when not in use.

### 15. ACKNOWLEDGEMENTS

This standard was developed with reference to:

- Therapeutic Goods Act 1989 (Cth)
- Guide to Good Manufacturing Practice for Medicinal Products
- Agricultural and Veterinary Chemicals Code
- Guidelines for the preparation and use of compounded pharmaceuticals produced by the Australian Veterinary Association Ltd.
- Victorian Pharmacy Authority Guidelines, The Victorian Pharmacy Authority, 2018;
- Pharmacy Board of Australia:
  - Guidelines on compounding of medicines – March 2015
  - Compounding of sterile injectable medicines – effective from 1 February 2018
  - Professional practice profile for pharmacists undertaking complex compounding – March 2015
- National Vaccine Storage Guidelines (*Strive for 5*); The Australia Government, Department of Health and Aging, 2014;
- Code of Practice for the Transport and Storage of Schedule 8 Substances
- NSW Pharmacy Council – Fact sheet: Raw materials used in Compounding – September 2018

### 16. Disclaimer

In case of any conflict or discrepancy between this document and legislation, the legislation prevails.