

# PACC

Version 1  
November 2024

## TASMANIAN PHARMACY AUTHORITY

ABN 34 562 572 269

Email: [registrar@pharmacyauthority.tas.gov.au](mailto:registrar@pharmacyauthority.tas.gov.au)

Telephone: 0417 752 348

### Application for approval of alterations to a pharmacy business premises to include a

### COMPLEX COMPOUNDING LABORATORY

Pursuant to section 71E of the Pharmacy Control Act 2001

This form is to be used if:	You are proposing to add/construct a complex compounding laboratory in a new or existing premises
This form should <b>not</b> be used if:	You are not constructing a complex compounding laboratory
The fee for this application is:	TBA

If you have any questions, please phone the Registrar.

Completed forms should be emailed to the [registrar@pharmacyauthority.tas.gov.au](mailto:registrar@pharmacyauthority.tas.gov.au) for consideration by the Tasmanian Pharmacy Authority. For consideration at the next meeting, forms must be submitted not later than ten days prior to the meeting date. Meetings are generally held on the first Wednesday of each month.

Incomplete forms will be returned, which may delay the outcome.

When alterations are approved, an in-principle approval will be issued for six (6) months. If alterations are not finalised during that time, you will need to request an extension. Any extensions are in effect for a further six (6) months from the date of extension. If alterations are not completed within a 12-month period from the date of the initial approval, then the approval will lapse and you will need to apply again, with full paperwork and another payment. Please note that approval of alterations by the Tasmanian Pharmacy Authority does not automatically infer that section 90 pharmacy approval will be granted by the Australian Community Pharmacy Authority (ACPA).

### 1.1 Premises

Pharmacy Name	
Address	
Phone	Fax
Email	
TPA identifier	
PY	

1.2 Owner(s) Please list the name and email address of each owner of this business i.e. the holder(s) of the Eligibility Certificate (these may be individuals or body corporates). If more space is required, please append additional pages.

Name	Email

1.3 Contact Details – for all correspondence in relation to this application; this must be an Owner or pharmacist-in-charge

Name
Phone
Email

## 2. Proposed Complex Compounding laboratory

The approved complex compounding laboratory must comply with all requirements of the current versions of the following:

- Pharmacy Control Act 2001,
- the Tasmanian Pharmacy Authority Guidelines,
- the Poisons Act 1971 and Poisons Regulations 2018,
- Australian Pharmaceutical Formulary and Handbook (APF).
- The Pharmacy Board of Australia Guidelines on compounding of Medicines
- Pharmaceutical Society of Australia Practice Standards
- *Therapeutic Goods Act 1989* and *Therapeutic Goods Regulations 1990* - section 55
- United States Pharmacopoeia (USP)

It is the obligation of the pharmacy owner to ensure all these requirements are met.

### 2.1 Please confirm that your proposed complex compounding laboratory offers the following:

	Y/N
A suitably trained, designated person, responsible and accountable for the performance/operation of the complex compounding facility (pharmacist or suitably qualified person)	
A dedicated area with full-height walls and a ceiling, one door for access and is large enough to allow orderly placement of equipment and materials	
Floor and surfaces (benches, shelves, cupboards) are in good condition, covered with non-shedding, impervious washable materials	
At least one bench (2m long and 90cm wide) as working space for compounding activities	
A sink with hot/cold running water or hand sanitising facilities (if sink is outside area)	
A clearly identifiable and dedicated bench to isolate raw materials/compounds not to be used or released to consumers	
Observable, identifiable area for the quarantine of finished products	
Approved powder containment hood for handling hazardous materials, (certified as meeting Australian Standards) with HEPA filtration and continuous pressure monitoring. (Please ensure you receive a certificate of compliance)	
Equipment to monitor and document the environmental conditions (temperature and if necessary, humidity) of the complex compounding laboratory	
Dedicated equipment and items that are used exclusively for complex compounding manufacture. (also must have separate designated equipment for cytotoxic or sterile manufacture)	
Professionally calibrated scales that comply with the Australian Pharmaceutical Formulary and Handbook (current version) requirements for accuracy and minimum weight.	
Appropriate fridge and freezer (if required) for compounding product/raw material storage with a monitored data logger	

Appropriate equipment and packaging for the dosage forms of compounded products (capsule machine, pH meter, child resistant closures, amber glass containers) which are stored off the floor	
Hot plate/stirrer or Standard operating procedure for complex compounding products that require heat.	
A spill kit	
Personal protective equipment (PPE) for all compounding staff.	
Standard operating procedures for the cleaning and maintenance of the space	
All required complex compounding references	

Are you compounding medicinal cannabis products?

If yes please answer below questions:

Is there dedicated equipment and an area that is used only for manufacturer of medicinal cannabis	
Are the ingredients used to compound medicinal cannabis and the final medicinal cannabis products that are classified as schedule 8 stored in a Pharmaceutical Services Branch approved enclosure/safe	

### 3. Floor Plan

You must attach a floor plan of the pharmacy premises, professionally drawn to scale to enable assessment of your application.

This floor plan must include the following details:

	√
The <b>entire</b> approved premises	
The location of any doors, windows, and skylights	
The location, dimensions, and area of the dispensary	
The boundary of the dispensary	
The 4m radius from the dispensary boundary	
The location and dimensions of any consultation/vaccination spaces	
The location of the refrigerator(s)	
The location of the approved narcotic safe(s)	

### 4. Floor plan of the complex compounding laboratory

You must attach a floor plan of the complex compounding laboratory, professionally drawn to scale, that includes fixtures and fittings which are noted as being present in Table 2.1

## 5. Declaration

I, \_\_\_\_\_ Ahpra Number \_\_\_\_\_

*Clearly PRINT the name of the Registered Pharmacist making this declaration*

Of

\_\_\_\_\_

*Address*

\_\_\_\_\_

*Position*

\_\_\_\_\_

*Either an Owner of this pharmacy, or the Pharmacist appointed by the Owner(s) to be regularly and usually in charge*

At

\_\_\_\_\_

*Name of the Pharmacy*

Declare that, to the best of my knowledge and understanding:

- a) the information provided in this application is true and correct
- b) all complex compounding activities undertaken in the pharmacy business premises will comply with all Legislation, Standards and Guidelines as issued from time to time
- c) I understand the premises will be inspected from time to time to ensure compliance with this declaration

Signed

Date

\_\_\_\_\_

**FALSE DECLARATION**

A person found guilty of making a false or misleading statement is guilty of an offence and is liable to a penalty of up to 100 penalty units (Section 68, Pharmacy Control Act 2001)

**PERSONAL INFORMATION PROTECTION STATEMENT**

Personal information will be collected from you by the Tasmanian Pharmacy Authority for the purpose of administering the ownership and registration of Tasmanian pharmacy business premises. Your personal information will be used for the primary purpose for which it is collected and may be disclosed to contractors and agents of the Tasmanian Pharmacy Authority, law enforcement agencies, Medicare Australia, the Australian Health Practitioner Regulation Agency, the Pharmaceutical Services Branch of the Department of Health and Human Services, courts and other organisations authorised to collect it. Your personal information will be managed in accordance with the Personal Information Protection Act 2004. You may access your personal information on written request to the Tasmanian Pharmacy Authority. You may be charged a fee for this service.