Complex compounding pharmacy self-inspection template

Complex compounding is defined under the Pharmacy Board of Australia (PBA) Guidelines for compounding medicines August 2024. The *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulation 1990* provide for the pharmaceutical compounding of medicines in certain circumstances

Purpose

This checklist has been developed for Tasmanian Pharmacy Authority (TPA) inspectors to conduct inspections on pharmacies which undertake complex compounding.

It can also serve as a self-audit tool for use by a pharmacist or non-pharmacist to assess their compounding practice to ensure it is compliant with complex compounding guidelines and Tasmanian state legislation. Proprietors / pharmacists that are considering providing complex compounding services in their pharmacies may also find the checklist useful for understanding the aspects of this practice.

The professional obligation of a complex compounding pharmacist should be determined with reference to relevant Commonwealth and State legislative instruments alongside current references, guidelines, standards, and resources.

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January 2025 (v 1.4)

TASMANIAN PHARMACY AUTHORITY

Email: registrar@pharmacyauthority.tas.gov.au **Telephone: 0417 752 345**

Pharmacy's full name: ……..

Complex compounding pharmacy Self-inspection Report Template

Pursuant to Pharmacy Control Act 2001 Part 4

Pharmacy's physical address: .....

Phone: …… Fax.....

EMAIL ADDRESS:

Owner: .....

Pharmacist in Charge.....*i.e., the pharmacist regularly and usually in charge*

Pharmacist-in-charge during the inspection: .....

Ahpra Registration Number of the Pharmacist-in-charge: ……

A. PERSONNEL: References and resources *Pharmacy Board Australia (PBA) Guidelines on compounding medicines 2024 s2 and s4 and s9, Ahpra Code of conduct 2022* *Pharmaceutical Society of Australia (PSA) National competency standards framework for pharmacist in Australia 2016 (Competency Standards 2016)* *PSA Professional Practice Standards 2023*		
	Yes No N/A	Evidence examples
A1: Are all compounding staff, dispensary technicians, interns, pharmacy students or pharmacists appropriately trained? A1a: Is there evidence of regular training and evaluation of personal hygiene and garbing? A1b: Is there evidence of evaluations of an individual's sterile technique(s)? A1c: Is there evidence of evaluation of individuals process validation? (ideally – 2 different drugs / 2 different dosage forms per technician per year sent for external validation)		Training records Certificates of completed training Copies of audits of hand hygiene and garbing Media fill testing results to demonstrate aseptic technique.
A2: Do compounding staff work directly under the supervision of the compounding pharmacist? NB: In cases where the pharmacy uses integrated software for compounding, the pharmacist is not required to be present in compounding room with technician. However, completed risk assessments and compounding worksheets can only be completed by supervising pharmacist.		Job descriptions of technicians Completed compounding worksheets
A3. Is base line and regular annual pathology monitoring performed (where required) of compounding staff?		
Comments:		

B. PUBLICATIONS (hardcopy/softcopy or website)	
Pharmacy Board Australia (PharmBA) Guidelines on compounding medicines 2024 Section 15 *APF 26 Compounding – Workplace safety*	Yes No N/a
B1. All current Tasmanian and Commonwealth legislation relating to pharmaceutical compounding are available to compounding staff and accessible from the compounding laboratory. - *Therapeutic Goods Act 1989*, *Therapeutic Goods Regulations 1990*, and relevant Therapeutic Goods Orders - *The Agricultural and Veterinary Chemicals Code Act 1994* - *Poisons Act 1978* (Tas) and *Poisons Regulations 2018* (Tas) - The current Poisons Standard (Uniform scheduling of Medicines and Poisons (SUSMP)). - *Work Health and Safety Act 2012* (Tas) - *Pharmacy Control Act 2001* (Tas)	
B2 Current references, guidelines, standards, and resources are available and accessible to compounding staff and from the compounding laboratory - Pharmacy Board of Australia (PharmBA) guidelines - Pharmaceutical Society of Australia (PSA) guidelines - Australian Pharmaceutical Formulary (APF) current edition - Tasmanian Pharmacy Authority (TPA) guidelines - Good Manufacturing Practice for Medicinal Products - Pharmaceutical Society of Australia Professional Practice Standards 2023- Standard 8: Compounding - The Society of Hospital Pharmacists of Australia (SHPA) Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments - Australian standards for clean rooms - SHPA Standards of Practice for the Provision of Oral Chemotherapy for the Treatment of Cancer (Hospital Pharmacy Departments only) - The Society of Hospital Pharmacists of Australia SHPA Guidelines for Medicines Prepared in Australian Hospital Pharmacy Departments - United States Pharmacopoeia (USP) November 2023– section 795 (non-sterile compounding) and 797 (sterile compounding)	
B3 Register of safety data sheets (SDS) for hazardous materials	
Comments: NB: United States Pharmacopoeia (USP) updated version released November 2023– section 795 (non-sterile compounding) and 797 (sterile compounding) – Sterile compounding – guided by the USP 797 which has been adopted by Australia – USP 797 - describes the requirements, including, responsibilities of compounding personnel, training, facilities, environmental monitoring etc	

C. PREMISES AND EQUIPMENT

References and resources:

Pharmacy Control Act 2001 s71E(3)
Tasmanian Pharmacy Authority (TPA) Guidelines v6.2 s12
PharmBA Guidelines on compounding medicines (2024)
PharmBA Guidelines for proprietor pharmacists
APF 26 Compounding – facilities and equipment and Handling and/or compounding hazardous materials – Guidance on safe handling
PSA Competency Standards 2016
PSA Professional Practice Standards 2023: Standard 8
Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons,(SUSMP))
USP-NF Hazardous Drugs – Handling in Healthcare Settings

	Yes No N/a	Evidence examples- photos
C1. There is a dedicated room for pharmaceutical compounding activities (away from routine dispensing activity and high traffic areas), which has floor to ceiling walls, at least one door, lockable if located in area easily accessible by the public?		Visual inspection
C2. The compounding room complies with the following: - An impervious floor - Impervious surfaces cleanable by washing - Adequate ventilation and lighting - At an ambient temperature of 25 degrees C or less which is monitored and maintained - Dedicated sink (stainless steel or impervious) with hot and cold running water. - Dedicate area clearly identifiable and labelled for use to isolate raw materials or compounded preparations not to be used or released. - At least one bench (2m long and 90cm wide) as working space for compounding activities. - Food and drinks are excluded from the room.		Visual inspection Documentation of environmental controls can include:(verification should occur annually) - Temperature/humidity logs - Airflow testing - Total particle count testing

C3. All equipment in the compounding laboratory - is used exclusively for compounding - is cleaned thoroughly before and after use? - If used for cytotoxic or sterile products is designated only for these uses. - Is in good clean working order (spatulas, mortar, and pestles (one of glass), funnel, stirring rods, ointment slabs) And includes (dependant on compounding requirements) - Scale(s) which are appropriate to the compounding work being undertaken and are calibrated at least every 12 months. - Date of calibration:…….. - A range of calibrated measures (200ml, 100ml, 10ml and 5ml dispensing measures) - Approved powder containment hood for handling hazardous materials. (certified as meeting Australian Standards) with HEPA filtration and continuous pressure monitoring - Filtration (as the final method of sterilization) equipment - - Appropriate heating source (hot plate/stirrer) - Appropriate fridge and freezer (if required) for compounding product/raw material storage with monitored data logger Comment:…… - A spill kit - 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.		Visual inspection Standard Operating procedure - Logs/records of surface sampling-conducted 1/12 at minimum. - Cleaning/cleaning logs - A schedule and method for establishing and verifying the effectiveness of sterilization and depyrogenation Certificate of compliance and recertification (6/12) for Powder containment hood, airflow testing and HEPA filter Filter integrity testing results (filter used should be attached to worksheet) Manual or electronic datalogger download reports (daily or weekly)
C4. Personal protective equipment (PPE) is available for all compounding staff. - Laboratory coats, surgical face mask, disposable gloves, hair, and beard covers. - PPE for handling hazardous materials, Eye protection, non-shedding, impermeable disposable gown/coveralls, appropriate respirator mask (P1,P2,P3) nitrile gloves, hair, beard, and shoe coverings. - Any other PPE advised in relevant Safety Data Sheets		Standard operating procedure Physical evidence of PPE

C5. Non-sterile compounding involving hazardous materials Activities are carried out to minimise: - cross contamination of product with other compounding products - exposure of hazardous materials to pharmacy staff. Risk management plan is in place and: - Addresses how risks will be controlled, to minimise risk to pharmacy staff (reasonably and practically) - There are records of identified risks which are regularly reviewed. - Standard Operating Procedures include: o Use of Safety Data Sheets for PPE and cleaning protocols o Exclusion criteria (pregnancy) o Streamlined workflow processes o No other compounding occurs during hazardous material compounding OR - Pharmacy has separate powder containment hood. OR - Separate and dedicated compounding laboratory (or room in compounding laboratory)		Standard operating procedures Risk Management Plan Standard operating procedures
C6: Medicinal Cannabis (MC) - Are there certificates of analysis from GMP (Good Manufacturing Practice) suppliers for MC distillates used for dilatation? - If there are raw ingredients or compounded preparations that are classified as Schedule 8 medicines (contain THC) are they stored in compliant safe, approved by Pharmaceutical Services Branch? - Is there separate equipment and area for the manufacturer of MC?		Certificates of analysis
Comment:		

D. QUALITY ASSURANCE References and resources Australian Pharmaceutical Formulary (APF) 26 Compounding- Good compounding Practice - Quality Assurance. PBA Guidelines on compounding medicines August 2024 - section 3 PSA Competency Standards 2016 PSA Professional Practice Standards 2023		
	Yes No N/A	Evidence examples
Raw materials: D1. Source: - Procured from acceptable manufacturers and of pharmacopeial standards - Certificate of analysis is provided - If quality of raw material is in doubt is independent testing conducted to confirm conforms to pharmacopeial standard. - Does repacking of raw ingredients occur? (this is considered a step in manufacture by TGA and requires TGA license.) Comment…… D2 Stored - in accordance with manufacturers recommended conditions or of the SDS. - Only in the compounding laboratory - Clearly and appropriately labelled. - If hazardous, in a separate dedicated area Comment…… D3. Is there adequate control of storage/movement of materials used for compounding in/out of compounding area?		Details for 1-3 random raw materials

D4 Systems: Is there a customised Standard Operating Procedures (policies and procedures) for: - Simple compounding - Non-sterile complex compounding (including compounding of hazardous materials) - Sterile complex compounding - -- SOP for assessing category of risk of compounded sterile preparation (CSP) (CAT1 to CAT5) - - SOP for assigning beyond use by dates (BUDs) categories based on assigned risk level of CSPs and compounded non-sterile preparations (CNSP) (Note: e.g. risk level CAT1 – sterile to sterile product compounding – BUD is immediate use, maximum is 28 days unless BUD studies support longer time frame; BUDs for CNSP defined under USP)		Standard operating procedure manual (hardcopy or electronic) Review of finished CSP worksheet Verbal explanation: Compounding pharmacist should be able to verbally explain assigning BUDs
D5. Documentation for each episode of complex compounding: - Completed risk assessment* - Completed compounding worksheets** - Prescription and dispensing records where applicable - Reports of adverse reactions - Evidence to support suitability and stability of non-pharmacopeial formulations or where these is no precedent for formulations from reputable references. *Compounding decision support and risk assessment tool available in the Pharmaceutical Society of Australia's Professional Practice Standards, Version 5 2017 **in accordance with Australian Pharmaceutical Formulary and Handbook 26 2024		Completed risk assessments, Completed compounding worksheets, Records and/or logs of incident reports/recalls/ training/ cleaning
D6. Documentation stating prescriptions are retained for 3 years		Standard operating procedure

E. RECORDS OF CIRCUMSTANCES TO COMPOUND MEDICINES References and Resources: Pharmacy Board of Australia, Guidelines on compounding of medicines, August 2024 Pharmaceutical Society of Australia, Professional Practice Standards 2023 Pharmaceutical Society of Australia, Competency Standards 2016 Australian Pharmaceutical Formulary and Handbook 26,2024 *Therapeutic Goods Act 1989* (Cth) Therapeutic Goods Regulation 1990 (Cth)		
	Yes No N/A	Evidence examples
E1a. Are compounded products for use in humans ONLY prepared as single unit issue in response to valid prescription or request for compounded non-prescription product? E1b. Quantities supplied are single unit or for prescription medicines, in quantity specified or confirmed by prescriber?		Prescriptions Visual inspection for Batch products or extra compounded products for patient
E2. Compounded preparations for animal use are only prepared as a single unit of issue in response to instructions received from a veterinary practitioner? The Agricultural and Veterinary Chemicals Code Act 1994 (Cth) (AgVet Code)		Veterinary prescriptions
E3. The compounding pharmacist is satisfied there is good clinical and pharmaceutical evidence to support the quality, stability, safety, efficacy, and rationality of any extemporaneous formulation used.		Compounding worksheets
E4. Is additional data and /or evidence obtained and documented to support the compounding of formulation without precedent in reputable references and/or inadequate published data (safety, efficacy, clinical, and pharmacokinetic)		Compounding worksheets

E5a. Labels of compounded preparations meet all legislative requirements - Approved pharmacopeial name or APF name - Amount / concentration of active and non-active ingredients (NB: if label cannot fit non-active then list must be provided to patient) - Directions for use - Cautionary and advisory labels (as required) - A statement product has been compounded - Patient/animal (for veterinary use only) details - Pharmacy details - Unique identifying code for dispensed medicine E5b. Does label of compounded product include storage conditions and expiry date of product (BUD or 28 days or less if based on reliable literature)		Review label and provide copy of label
E6a. Batch compounding is not undertaken in anticipation of prescription/requests/orders, unless identical prescription/requests/orders exist for individual named patients. E6b. A risk assessment is conducted prior to compounding batch preparations, where multiple units of issue of preparation?		Compounding worksheets
E7. Counselling and written information is provided to patient or agent		CMI examples
E8. Does the pharmacy provide a complex compounding service to a pharmacy or pharmacies acting as a third party supplier? If YES is there i. a written agreement which includes the responsibilities of each pharmacy? ii. SOP for accepting, processing and supply of the complex compounded prescription iii. Documentation of risk assessment of the patient being supplied the complex compounded preparation via third party supply Reference QC2020 5.3.1		Example of written agreement SOP 3rd party patient risk assessment documents
Comment: Written agreement should include, transfer of prescriptions and privacy implications, conduction of risk assessment, payment, counselling, identification checks and storage of compounded medicines. NOTE: Referring pharmacy must not take payment for the compounded preparation or request a handling fee for the prescription. Compounding pharmacy should take payment at initial consultation and provide referring pharmacy with ID/sign off sheet for patient to complete at supply. The compounded product must be dispensed and labelled by the compounding pharmacy, and the referring pharmacy MUST NOT re-dispense or re-label the product.		

F. **ADVERTISING of compounded preparations to the public**

Reference and resources:

Therapeutic Goods Advertising Code, *Therapeutic Goods Regulations 1990* (Cth) and *Therapeutic Goods Act 1989*(Cth)

PBA Guidelines on compounding of medicines August 2024, Guidelines 14- Advertising.

(Appendix H SUSMP - https://www.tga.gov.au/resources/publication/scheduling-decisions-final/final-scheduling-decisions-and-reasons-nces-and-appendix-h/11-appendix-h)

Pharmacy Guild Guidelines - https://www.guild.org.au/resources/business-operations/Advertising-of-therapeutic-goods-and-health-services-by-pharmacies

	Yes No N/A	Evidence examples
F1a. Is there advertising for Schedule 4 or 8 medicines or schedule 3 not listed in appendix H of SUSMP? F1b. Is there advertising for non-scheduled, S2 and S3 included in Appendix H of SUMP medicines - Does it include information on the efficacy of the product - Is the advert pre-approved by Department of Health if placed in billboards, newspapers, magazines, television, and others Comment _____ Pharmacist in charge should have approval documentation		Copy of advertising
F2. Advertising adheres to Therapeutic Goods Advertising Code – current edition- https://www.tga.gov.au/how-we-regulate/advertising/how-advertise/advertising-guidance/resources/resource/guidance/guidance-applying-advertising-code-rules Pharmacist in charge to provide this information		
Comment:		

Resources and references used to complete:

1. Pharmacy Board of Australia, Guidelines on compounding of medicines, August 2024
2. Pharmaceutical Society of Australia, Australian Pharmaceutical Formulary and Handbook 26,2024
3. Pharmaceutical Society of Australia, National Competency Standards Framework for Pharmacists in Australia, 2016
4. Pharmaceutical Society of Australia Professional Practice Standards 2023
5. Australian Pharmaceutical Formulary (APF) 26- Compounding
6. Pharmacy Council of New South Wales, Premises and equipment guidance for non-sterile complex compounding, 2019
7. The current Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons) (Cth) in force as proclaimed in Tasmania under the Poisons and Therapeutic Goods (Poisons List) Proclamation 2016
8. *Therapeutic Goods Act 1989 (Cth)*
9. *Therapeutic Goods Regulation 1990 (Cth)*
10. *The Agricultural and Veterinary Chemicals Code Act 1994* (Cth) (AgVet Code)
11. Therapeutic Goods Order No. 80 Child-Resistant Packaging Requirements for Medicines
12. Therapeutic Goods Order No. 91 Standard for Labels of prescription and related medicines
13. Therapeutic Goods Order N. 92 Standard for labels of non-prescription medicines
14. Pharmacy Board of Australia, Guidelines for dispensing of medicines, 2015
15. Pharmacy Board of Australia, Guidelines for advertising regulated health services, 2014
16. *Therapeutic Goods Advertising Code 2018*
17. *Poisons Regulations 2018(TAS)*
18. *Poisons Act 1971*
19. *Pharmacy Control Act 2001*
20. Tasmanian Pharmacy Authority Guidelines v6.2
21. United States Pharmacopoeia (USP) November 2023 – section 795 (non-sterile compounding) and 797 (sterile compounding)
22. Quality Care 2020 5.3