VICTORIAN PHARMACY AUTHORITY (VPA)

SELF AUDIT FORM - PHARMACY

Introduction:

This document is designed to assist licensees and pharmacists to audit their compliance with key requirements of the *Pharmacy Regulation Act 2010* (**the Act**), Victorian Pharmacy Authority Standards (**VPA Standards**) and Guidelines (**VPA Guidelines**) and good pharmacy practice. In relation to good pharmacy practice, the VPA recognises the registration standards, guidelines, codes, and policies issued by the Pharmacy Board of Australia and has regard to the standards, codes and guidelines issued by the Pharmaceutical Society of Australia, The Society of Hospital Pharmacists of Australia, Victorian Department of Health and Therapeutic Goods Administration.

It is not a requirement to send the completed form to the Victorian Pharmacy Authority.

When to use the self-audit form:

It is recommended that newly established services or high-risk areas are audited at least twice a year. As systems become stable and well documented, the audit frequency can reduce to at least annually. There are separate self-audit forms for specific pharmacy services.

How to use the self-audit form:

a) Check the Act

Before completing the self-audit, it is important to know the basics of the Act (especially the Schedule to the Act), the VPA Standards and Guidelines and how they apply to your pharmacy.

b) Check your records and procedures

While the audit checklist typically calls for a Yes, No or N/A response, take the time to check that your records or procedures do in fact demonstrate compliance. As a guide, take an adequate sample of your records (at least 10%), and confirm that:

- Records have been filled in with all the required information, signatures and dates;
- Procedures do reflect good pharmacy practice and are being followed by all applicable employees. Have the procedures been recently reviewed and updated? Do the procedures reflect the specific conditions and circumstances that apply in your pharmacy?

When answering a question, record 'No' if there is only partial compliance with the requirement as this will help you identify areas to focus your attention to improve the provision of pharmacy services.

Questions highlighted in green represent high-risk areas routinely covered during VPA inspections. These may include frequently observed non-compliances.

If significant non-compliance with the VPA standards is identified during the inspection, the inspector may extend the scope of the inspection to include compliance with VPA guidelines and good pharmacy practice.

c) Review the findings

Typically, if the answer to a question is 'Yes', then the pharmacy is likely to comply with the requirements.

If the self-audit is conducted by the pharmacist regularly and usually in charge (PRUIC) or by different pharmacist(s), it is important that all the findings are reviewed by the licensee.

d) Identify actions to address your compliance issues

Finally, if the checklist has identified deficiencies or areas for improvement, identify appropriate action(s) to rectify the issue(s) and prevent a reoccurrence in the future.

If the licensee openly discusses the issue(s) identified by the self-audit with relevant employees, it is more likely that appropriate action(s) are identified to rectify the issues and introduce appropriate changes in culture, awareness, and a focus on continual improvement.

Assigning who is responsible for implementing the action and a due date will allow the process to be monitored and addressed in a timely manner.

VICTORIAN PHARMACY AUTHORITY (VPA)
SELF AUDIT FORM - PHARMACY

Pharmacy Name and Address:

Postcode
Date of Audit:

Pharmacy Services:

☐ Dispensing and counselling	☐ Simple compounding	☐ Pharmacotherapy (Opioid Replacement Therapy, ORT)
☐ Injections (incl. vaccination)	☐ Dose Administration Aids (DAA)	☐ Complex compounding – Non-sterile
☐ Other		

1.	**LICENSEE RESPONSIBILITIES**	**Requirement met**		
		Yes	**No**	**N/A**
1.1	Compliance			
1.1.1	Compliance with the requirements of the Act, VPA Standards and conditions imposed by the Authority	☐	☐	
	Is the licensee aware of and complies with all obligations and requirements in relation to holding a licence and registration of a pharmacy premise?	☐	☐	
	Is the licensee aware of the ramifications of not meeting the requirements of the Act including the Schedule to the Act?	☐	☐	
	Has the VPA been notified of any change(s) to commercial arrangement(s) affecting the operation of the pharmacy business?	☐	☐	☐
	Is the licensee's name (as shown on the VPA's public register) clearly displayed at all public entrances to the pharmacy (company name if applicable)?	☐	☐	
1.1.2	Ensuring the delivery of pharmacy services complies with relevant legislation and follows good pharmacy practice	☐	☐	
	Does the licensee have effective oversight and management of all pharmacy services provided?	☐	☐	
	Has the licensee sought approval from the VPA before authorising, causing, or permitting any other person to carry on a business or activity within the registered pharmacy premises?	☐	☐	☐
	Is the pharmacy personally supervised by a registered pharmacist, whenever it is open for business?	☐	☐	
	When the pharmacy is NOT open for business, is access to the pharmacy only allowed if a registered pharmacist is present?	☐	☐	
1.1.3	Ensuring all medicines and poisons are managed in accordance with legislation and good pharmacy practice	☐	☐	
	Are all scheduled medicines stored and/or displayed in accordance with Drugs and Poisons legislation?	☐	☐	
	Are S8 and S9 poisons stored in a lockable storage facility (safe or vault) which meets the requirements of Drugs and Poisons legislation?	☐	☐	
	Is the safe or vault dedicated to the storage of S8 and S9 poisons?	☐	☐	
	Are all S8 poisons stored in a safe or vault?	☐	☐	
	Is the dispensary equipped with adequate storage capacity for S8 and S9 poisons which facilitates their accurate selection?	☐	☐	
	Is the safe or vault key kept on the person of a pharmacist or otherwise secured e.g., in a key safe (may have combination lock) which provides security equivalent to that of the safe or vault?	☐	☐	
	Are all S4 poisons stored in the dispensary or in a locked storage facility within the pharmacy premises?	☐	☐	

VICTORIAN PHARMACY AUTHORITY (VPA)
SELF AUDIT FORM - PHARMACY

1.	**LICENSEE RESPONSIBILITIES**	**Requirement met**		
		Yes	**No**	**N/A**
	Is there a system in place to ensure that medicines are not re-used after dispensing and after they have left the pharmacy?	☐	☐	
	Are returned medicines including those returned from nursing homes and those in dose administration aids stored in a secure manner and disposed of safely and regularly (e.g., use of RUM bins)*?*	☐	☐	
	Does the pharmacist on duty routinely monitor the sale of Pharmacy Medicines by non-pharmacist members of staff?	☐	☐	
	Is the professional service area used solely for the display and storage of products for therapeutic use and information about them?	☐	☐	
	Is the sale of medicines particularly those known to be abused or misused supervised and monitored?	☐	☐	
	Are S3 poisons displayed or stored in a manner to prevent self-selection by the public, and in a manner that will not promote or draw undue attention to them?	☐	☐	
	For S3 poisons containing pseudoephedrine, is all stock kept out of public view?	☐	☐	
	For S3 poisons containing pseudoephedrine, is the quantity of stock for sale kept to no more than that sufficient for 1 week's sales from the pharmacy?	☐	☐	
	Is the pharmacist personally involved and takes all reasonable steps to ensure a therapeutic need exists before supplying an S3 poison?	☐	☐	
	Does the pharmacist personally deliver/supervise the supply of and provide directions for use of S3 poisons?	☐	☐	
	Is only one package of an S3 poison supplied at a time (unless there are exceptional circumstances, and the supply is documented)?	☐	☐	
1.2	Management			
1.2.1	There is appropriate management of the pharmacy business by acting or appointing a pharmacist to be regularly and usually in charge and notifying the Authority in each case			
	Has the VPA been notified of the pharmacist regularly and usually in charge (PRUIC)? (Note: a pharmacist can only be PRUIC at one pharmacy at a time)	☐	☐	
	Is the name of the pharmacist who is regularly and usually in charge of the pharmacy always clearly displayed in the professional service area of the pharmacy?	☐	☐	
1.2.2	Ensuring that employed pharmacists hold appropriate and current registration			
	Is there a system in place to ensure all employed pharmacists (including locums) hold current pharmacy registration and duties are consistent with any registration conditions?	☐	☐	
1.2.3	Ensuring that all staff are suitably qualified and trained			
	Do all employed dispensary technician(s)/assistant(s) have appropriate education, training recognised by the pharmacy Board of Australia, and experience?	☐	☐	
	Is evidence of training undertaken by staff recorded and held at the pharmacy?	☐	☐	
	Do all staff have written position and duty descriptions which accurately reflect their role (e.g., Pharmacist, Pharmacist Immuniser, Dispensary technician/assistant, Compounding assistant/technician, etc.)?	☐	☐	
	Do all staff have training records which are regularly updated and accurately reflect the status of training undertaken? (e.g., recognised compounding and immuniser courses, current First aid and CPR certificates)	☐	☐	
	Do staff understand and follow the pharmacy's policies and procedures?	☐	☐	
	Do pharmacists work within their level of competence?	☐	☐	
	Do staff only perform roles for which they have been trained?	☐	☐	

VICTORIAN PHARMACY AUTHORITY (VPA)
SELF AUDIT FORM - PHARMACY

1.	**LICENSEE RESPONSIBILITIES**	**Requirement met**		
		Yes	**No**	**N/A**
	Are there different sets of skills, knowledge and experience within the team which reflect the range of services provided?	☐	☐	
	Is there ongoing learning and development of the pharmacy team (i.e., staff keep their knowledge and skills up to date)?	☐	☐	
	Do staff know when and how to raise a concern with the pharmacy licensee(s)?	☐	☐	
1.2.4	Ensuring that there are enough suitably qualified and trained staff to support service demands and the safe and effective provision of pharmacy services			
	Are there sufficient pharmacist(s) or dispensing assistant(s) on duty to manage the dispensing workload?	☐	☐	
	Is there sufficient suitably qualified staff on duty for the services provided, with clear lines of accountability?	☐	☐	
	Can the pharmacy clients easily identify who are staff and the role that they are performing?	☐	☐	
	Is there a staffing plan which considers the specific services provided by the pharmacy?	☐	☐	
	Is there staff contingency planning for short and long-term staff absence, whether planned or unplanned?	☐	☐	
1.2.5	Ensuring that staff comply with professional and legal obligations			
	Do pharmacist(s) uphold their professional responsibilities when delegating work to dispensary technicians/assistants under their supervision?	☐	☐	
	Is a pharmacist directly supervising all staff carrying out dispensing or compounding duties?	☐	☐	
	Does the licensee manage any personal or organisational goals, incentives, or sales targets without compromising the professional judgement of staff to deliver safe and effective pharmacy services?	☐	☐	
1.2.6	Ensuring that staff have access to current reference texts			
	Do pharmacists (including locums) have ready access to reference texts (including online references) during the dispensing process?	☐	☐	
1.3	Records			
1.3.1	Ensuring records relating to pharmacy services are created, stored and retained in accordance with relevant legislation and good pharmacy practice			
	Is the S8 register reconciled with S8 poisons on hand, orders received, and prescriptions or orders supplied?	☐	☐	
	Are all records relating to pharmacy services created, stored, and retained in accordance with relevant legislation (including *Privacy Act 1988*)?	☐	☐	
1.3.2	Records containing consumer's personal and health information are secure from theft, misuse, interference, loss, unauthorised access, modification or disclosure			
	Are patient records (both physical and digital) securely stored in the dispensary or in a locked facility?	☐	☐	
	Are cyber security basics in place to ensure computers and sensitive data remain secure (e.g., access to personal and health information is controlled by individual password protection to authorised persons only, using up-to-date anti-virus scanner and firewall software, use of multifactor authentication, ensuring internet networks are password protected and secure, staff training and procedures for responding to cyber incidents)?	☐	☐	
	Are records or information (both physical and digital records) which are no longer required to be retained appropriately destroyed?	☐	☐	
	Are arrangements in place to ensure that client information cannot be obtained by others from discarded documents?	☐	☐	

VICTORIAN PHARMACY AUTHORITY (VPA)
SELF AUDIT FORM - PHARMACY

1.	**LICENSEE RESPONSIBILITIES**	**Requirement met**		
		Yes	**No**	**N/A**
1.3.3	Records for Schedule 8 and 9 poisons are in accordance with Drugs and Poisons legislation			
	Are transactions involving S8 and S9 poisons recorded in the drug register as soon as practicable after completing the transaction?	☐	☐	
	Does the S8 register show the true and accurate balance of each S8 poison remaining after each transaction?	☐	☐	
	Are discrepancies in the S8 register investigated without delay?	☐	☐	
	Are returned S8 poisons awaiting destruction recorded in the drug register?	☐	☐	
	Are any unresolved discrepancies notified without delay to the Department of Health, Medicines and Poisons (email: dpcs@health.vic.gov.au)?	☐	☐	
1.4	Policies and procedures			
1.4.1	Policies and procedures in place which are relevant to the services provided and activities being undertaken at the registered premises.			
	Are there adequate policies and procedures in place to cover: a) the pharmacy operation, b) management and governance arrangements; and *c)* all services provided by the pharmacy?	☐	☐	
1.4.2	Policies and procedures are clearly documented, easily accessible, regularly reviewed and updated as part of an effective governance arrangements.			
	Are policies and procedures clearly documented, readily accessible, regularly reviewed and updated?	☐	☐	
	Are only current versions of all policies and procedures in-use?	☐	☐	
	Are policies and procedures written, reviewed and approved by personnel with appropriate knowledge and expertise?	☐	☐	
	Are policies and procedures reviewed and updated on a regular basis to ensure that they reflect current good pharmacy practice and changes in legislation?	☐	☐	
1.4.3	Policies and procedures are readily available to all staff and are being followed.			
	Are current versions of policies and procedures easily accessible (either physical copy or electronic read-only) by all relevant staff?	☐	☐	
	Is there a process in place to observe, monitor and document staff compliance with policies and procedures?	☐	☐	
	Is there evidence that policies and procedures are being followed (e.g., all records are being correctly filled, reviewed and stored)	☐	☐	
1.5	Quality improvement and risk management			
1.5.1	Appropriate systems in place to monitor and review the safety and quality of pharmacy services as part of ongoing improvement activities.			
	Is there a process or system in place to identify and implement measures to improve the quality and safety of provided pharmacy services?	☐	☐	
	Are improvement activities clearly documented including agreed actions, responsibility for completion of actions and due dates, evidence of implementation and follow up reviews?	☐	☐	
	Is there a culture of openness, honesty, and learning that promotes the raising of issues with the pharmacy licensee(s)?	☐	☐	

VICTORIAN PHARMACY AUTHORITY (VPA)
SELF AUDIT FORM - PHARMACY

1.	**LICENSEE RESPONSIBILITIES**	**Requirement met**		
		Yes	**No**	**N/A**
1.5.2	Appropriate systems in place to identify, investigate and monitor incidents, adverse events and near misses.			
	Are incident records created and retained in a dedicated readily accessible file?	☐	☐	
	Is there a process or system in place to ensure that incidents, adverse event and near misses are consistently and routinely identified, investigated and monitored?	☐	☐	
	Does the monitoring of incidents, adverse events and near misses (e.g., identifying trends or similar contributing factors) identify quality improvement actions?	☐	☐	
	Is there a reliable system for inter-staff professional communication?	☐	☐	
1.5.3	Appropriate systems in place to identify and manage the risk associated with providing pharmacy services.			
	Are there risk management plans for all provided pharmacy services?	☐	☐	
	Are the risk management plans regularly reviewed and the implementation of risk mitigation controls or actions monitored?	☐	☐	
	Do staff have a good understanding of the risks involved in providing pharmacy services and the risk mitigation strategies implemented?	☐	☐	
	Are suitable insurance arrangements in place for the pharmacy services provided?	☐	☐	

VICTORIAN PHARMACY AUTHORITY (VPA)
SELF AUDIT FORM - PHARMACY

2.	**PREMISES**	**Requirement met**		
		Yes	**No**	**N/A**
2.1	Essential and ongoing requirements			
2.1.1	Registered premises shall comply with relevant requirements of the Schedule to the Act on an ongoing basis			
	Are registered premises maintained in a clean and hygienic manner?	☐	☐	
	Is the general physical security of the premises assured, and the control of keys or other entry devices is restricted to registered pharmacists authorised by the person carrying on the pharmacy business?	☐	☐	
	Does a registered pharmacist oversee the area of the pharmacy where pharmacy services are provided?	☐	☐	
	Is there no access to the dispensary of the pharmacy except under the direct supervision of a registered pharmacist?	☐	☐	
	Do non-dispensary staff members store their personal belongings and take meal and tea breaks outside the dispensary?			
	Are confidential discussions able to occur between pharmacists and clients?	☐	☐	
	Are 'cash and wrap' or 'checkout' counters arranged to ensure that the identity of a medicine being purchased by the client cannot be known by another client at the counter?	☐	☐	
	Are 'cash and wrap' or 'checkout' counters arranged to ensure that the identity of a dispensed medicine being taken to the counter cannot be known by other clients in the pharmacy?	☐	☐	
2.1.2	Registered premises shall be maintained in an organised, uncluttered state			
	Are registered premises maintained in an organised, uncluttered state?	☐	☐	
	Is clutter and/or items not associated with dispensing removed from dispensing benches?	☐	☐	
2.2	Alterations			
2.2.1	Authority approval shall be obtained prior to making any significant alteration to registered premises			
	Has the VPA approved any significant alterations to the premises?	☐	☐	☐
2.3	Security			
2.3.1	The doors, windows, skylights, walls and ceilings of registered premises shall be substantially constructed and secured to prevent unauthorised access.			
	Are all perimeter doors that open to secluded or non-public areas either roller shutters or solid core doors reinforced with heavy gauge metal sheeting or protected by a substantial metal security grille door?	☐	☐	
	Are perimeter windows to secluded or non-public areas fitted with bars or security grilles?	☐	☐	
	Are skylights fitted with bars or security grilles or substantial locks if able to be opened?	☐	☐	
	Do dispensary doors that cannot be readily supervised close automatically and are not able to be opened from the outside without a key, code or swipe card?	☐	☐	
2.3.2	There shall be adequate perimeter security measures in place to prevent and deter unauthorised access			
	Are the premises secure and safeguarded from unauthorised access?	☐	☐	
	Are the different parts of the premises properly situated and are they secure and suitable for the purpose for which they are to be used?	☐	☐	
	Are perimeter doors fitted with a locking system that meet the requirements of the building code?	☐	☐	
	Are other measures in place to prevent entry through roofs or ceilings when the premises are not lawfully occupied (e.g., floor to roof walls, steel mesh welded or mechanically fixed to the underside of roofing purlins or structural roof beams throughout the whole roof space before a suspended ceiling system is installed or ceiling space alarm sensors are installed)?	☐	☐	

VICTORIAN PHARMACY AUTHORITY (VPA)
SELF AUDIT FORM - PHARMACY

2.	**PREMISES**	**Requirement met**		
		Yes	**No**	**N/A**
2.3.3	The reregistered premises shall be fitted with a functional 24-hour monitored intrusion detector alarm which is a) is monitored by an appropriately graded monitoring centre or an onsite security service approved by the Authority in special circumstances b) covers all areas where medicines and poisons are kept.			
	Is the pharmacy fitted with a functional electronic intruder alarm fitted which is control room monitored to a central agency on a 24-hour basis?	☐	☐	
	Does the central agency, monitoring the alarm system, hold a security firm licence?	☐	☐	
	Does the central agency have facilities that are graded in accordance with Australian Standard 2201.2:2022 – Alarm and electronic security systems Part 2: Monitoring centres – to grade 1, 2 or 3?	☐	☐	
	Does the electronic alarm cover the perimeter of the pharmacy as well as all areas where medicines are kept including the dispensary, Schedule 8 storage facilities, rooms used to store dispensed medicine for packing into dose administration aids, the professional service area and storerooms?	☐	☐	
2.4	Design, Layout and Condition			
2.4.1	The dispensary shall be a private area, dedicated to tasks associated with the dispensing, supply and compounding of medicines and secure storage of medicines and patient records.	☐	☐	
	Does the design of the dispensary prevent members of the public from entering the dispensary unnoticed by the pharmacist on duty?	☐	☐	
	Is the dispensary restricted to trained dispensary staff only?	☐	☐	
	Does the design of the dispensary or the location of counters or other fixtures in the public area of the pharmacy prevent clients approaching and standing directly in front of the dispensary, except at designated service points, and distracting pharmacist or reading private documents that may be on the dispensary bench?	☐	☐	
	Are all non-dispensary tasks performed outside the dispensary (e.g., POS data entry, storage of non-dispensary stock, storage of display materials, promotional activities)?	☐	☐	
	Is the pharmacy arranged so that the dispensary is not used as a thoroughfare to access “back of house” areas?	☐	☐	
2.4.2	The dispensary shall be fitted with: a) a sink with integrated drainer, that is supplied with hot and cold running water and connected to an appropriate waste outlet b) refrigeration which is dedicated to and appropriate for the storage of medicines, with adequate temperature monitoring c) an appropriate number of suitably equipped dispensing stations d) sufficient free working space and area/s for equipment storage and use e) a storage system which provides for the safe custody and accurate selection of medicines f) a dedicated storage facility for Schedule 8 and 9 poisons which complies with legislation, provides adequate storage for poisons on hand at all times and facilitates their accurate selection.			
	Is the dispensary area fit for purpose and equipped with sufficient workspaces for the level and type of services provided?	☐	☐	
	Does the dispensary include: a) a sink with integrated drainer and hot and cold running water	☐	☐	
	b) a refrigerator dedicated to and appropriate for the storage of medicines?	☐	☐	
	c) one dispensing station for each 150 prescriptions or part thereof dispensed on a typical day?	☐	☐	

VICTORIAN PHARMACY AUTHORITY (VPA)
SELF AUDIT FORM - PHARMACY

2.	PREMISES	Requirement met		
		Yes	No	N/A
	d) a specific bench or bench area of at least 0.6m^2 located near to the sink for the simple compounding or preparation of medicines and that also provides storage for compounding equipment?	☐	☐	
	a specific bench or bench area of at least 0.6m^2 for the unpacking and sorting of dispensary orders received?	☐	☐	
	a specific bench or bench area of at least 0.6m^2 for dispensary clerical and research use?	☐	☐	
	a specific bench or bench area of at least 0.6m^2 for a pharmacotherapy program (if 20 or more patients per day) that is not accessible to the public and provides for secure storage of in-use S8 medicines?	☐	☐	
	a specific bench or bench area of at least 1m^2 dedicated to the filling of dose administration aids (DAAs) (if regularly fill DAAs for 15 or more patients per week) and a secure storage for dispensed medicines?	☐	☐	
	a specific bench or bench area of at least 1m^2 dedicated to the filling of dose administration aids (DAAs) (if regularly fill DAAs for 15 patients per week) and a secure storage for dispensed medicines?	☐	☐	
	e) a medicine storage system that facilitates the accurate selection of medicines?	☐	☐	
	f) a dedicated facility for Schedule 8 and 9 poisons which complies with legislation, always provides adequate storage for poisons on hand and facilitates their accurate selection	☐	☐	
	Does each dispensing station include: a) a dispensing bench of at least 0.6m^2?	☐	☐	
	b) a computer/network with access to dispensing software?	☐	☐	
	c) a keyboard?	☐	☐	
	d) a screen?	☐	☐	
	e) a dedicated scanner?	☐	☐	
	f) a dedicated printer for labels?	☐	☐	
	g) a dedicated printer for repeat forms	☐	☐	
	h) adequate stationary	☐	☐	
	i) being located near a printer that prints Consumer Medicine Information (CMI)? (The CMI printer may serve multiple dispensing stations)	☐	☐	
	Is there a dedicated prescription reception and counselling point for each dispensing station used to dispense prescriptions?	☐	☐	
	Are the dedicated prescription reception and counselling points each fitted with opaque privacy screens rising not less than 600 mm above the bench to form a privacy booth or be otherwise arranged or situated to provide privacy?	☐	☐	
	Is the drug refrigerator to be monitored to ensure potential cold chain breaches are identified at the earliest opportunity and investigated using a data logger in accordance with VPA Guidelines and National Vaccine Storage Guidelines, Strive for 5?	☐	☐	
	Is each storage facility for S8 and S9 poisons constructed and attached in accordance with the Drugs, Poisons & Controlled Substances Regulations 2017 and guidance issued by the Department of Health?	☐	☐	
2.4.3	The dispensary shall be well lit, adequately ventilated and temperature controlled to maintain the integrity of medicines and provide for personal comfort.			
	Are all medicine storage areas serviced by a thermostatically controlled air-conditioner that maintains storage temperatures so that the temperature does not exceed 25ºC (even when the pharmacy is not open for business)?	☐	☐	
	Is there adequate lighting over the dispensary workspaces?	☐	☐	

VICTORIAN PHARMACY AUTHORITY (VPA)
SELF AUDIT FORM - PHARMACY

2.	**PREMISES**	**Requirement met**		
		Yes	**No**	**N/A**
2.4.4	There shall be hygiene and infection prevention measures in place which are appropriate for the pharmacy services being provided.			
	Have appropriate hand hygiene, cleaning and disinfection measures been implemented to prevent the spread of infection or cross-contamination (e.g., hygiene and cleaning procedures and use of cleaning records, specific hygiene and infection prevention training)?	☐	☐	
2.5	Equipment			
2.5.1	Equipment shall be safe to use and fit for purpose.			
	Is equipment obtained from reputable source(s)?	☐	☐	
	Is equipment safe to use and fit for purpose?	☐	☐	
	Are all refrigerators dedicated to the storage of medicines fitted with a temperature data logger to allow the effect of any malfunction on the integrity of the medicines to be assessed?	☐	☐	
	Is equipment safeguarded from unauthorised access?	☐	☐	
2.5.2	Equipment shall undergo regular maintenance, including routine calibration or servicing			
	Is there an equipment register/log which records all equipment and the type and frequency of any maintenance, servicing and/or calibration activities to be undertaken?	☐	☐	
	Is the company selected to provide equipment maintenance and calibration services, appropriately accredited to provide the service?	☐	☐	
	Are traceable calibration reference standards used?	☐	☐	
	Is there a system to monitor that scheduled equipment maintenance and calibration is undertaken as planned and any test results or performance checks performed are reviewed to decide that that equipment continues to be fit for purpose?	☐	☐	
2.5.3	Equipment shall be operated safely, in accordance with standard operating procedures and within the manufacturer's specified operating range			
	Are there procedures documenting how equipment is to be operated including defining appropriate environmental conditions, safe operating range, and minimum weighing amounts for scales?	☐	☐	
	Is there a process to decommission equipment that is no longer safe to operate or no longer complies to specification or calibration requirements?	☐	☐	
2.5.4	Equipment shall be routinely cleaned			
	Are there procedures documenting how individual or similar equipment is to be cleaned and stored?	☐	☐	
	Is there sufficient detail in the cleaning procedure(s) to ensure consistent results (e.g., is the strength of detergent defined, is scrubbing required/or not to be performed as it potentially damages product contact surfaces, how many rinses are required to remove debris and detergent or solvent residues, how is equipment dried and inspected)?	☐	☐	
	Is equipment always stored in a clean and dry state after use?	☐	☐	
	Is clean equipment labelled with date when last cleaned?	☐	☐	
	Is clean equipment visually inspected before use and if dirty is recleaned prior to use?			
	Is cleaning equipment (if not single use) appropriately cleaned and stored between use?	☐	☐	
2.5.5	Maintenance records shall be kept and standard operating procedures shall be current and readily available.			
	Is equipment appropriately maintained (including calibration and testing at regular intervals and appropriate performance and maintenance logs kept)?	☐	☐	
	Are equipment maintenance and calibration processes documented?	☐	☐	

VICTORIAN PHARMACY AUTHORITY (VPA)
SELF AUDIT FORM - PHARMACY

2.	**PREMISES**	**Requirement met**		
		Yes	**No**	**N/A**
	Are maintenance and/or calibration reports provided by service companies comprehensive? E.g., do calibration reports include: a) description of equipment (make, model and identifying serial numbers) b) calibration date c) national/international standards to which the equipment was calibrated d) calibration results e) uncertainty estimates f) accreditation and traceable certificates confirming the calibration's validity	☐	☐	
2.5.6	Registered premises shall be equipped with the minimum equipment required for simple compounding.			
	Is the dispensary equipped with a set of approved Class 1 or Class 2 scales in good working order, the operating instructions for which, including minimum weighable mass, are prominently displayed?	☐	☐	
	Do the scales have the appropriate sensitivity for the range of work being undertaken?	☐	☐	
	Is the dispensary equipped with an adequate range of accurately calibrated measures e.g., 10ml, 50ml,100ml & 200ml?	☐	☐	
	Is the dispensary equipped with a mortar and pestle, an ointment slab and range of spatulas?	☐	☐	
2.5.7	Appropriate equipment shall be used for the handing and compounding of hazardous materials to ensure that staff and the public are not put at risk and the integrity of the product is maintained.			
	Is a decision to handle or compound hazardous materials in a pharmacy setting documented (e.g., through a risk assessment or a similar document which identifies how the hazard and its associated risk will be controlled)?	☐	☐	
	Do the control(s) selected provide the highest level of protection for staff and public (e.g., A hierarchy of controls from most effective to least effective include elimination, substitution, engineering controls (such as a containment cabinet in a separate room) and personal protective equipment (PPE))?	☐	☐	
	Is the selection of PPE also based on the functionality, fit, comfort and ergonomics of the PPE for each employee?	☐	☐	
2.6	Reference Texts			
2.6.1	There shall be a range of current reference texts relevant to the pharmacy services provided at the premises			
	Is the dispensary equipped with a range of current reference texts relevant to the pharmacy services provided?	☐	☐	
	Are relevant current compounding references readily available to compounding staff (e.g., APF, Martindale, Safety data sheets (SDSs))?	☐	☐	☐
	Are relevant current vaccination references readily available (e.g., Australian Immunisation Handbook, National Vaccine Storage Guidelines: Strive for 5)?	☐	☐	☐

VICTORIAN PHARMACY AUTHORITY (VPA)
SELF AUDIT FORM - PHARMACY

Specific pharmacy service checklists included in this self-audit

A ☐ Dispensing	B ☐ Pharmacotherapy (Opioid Replacement Therapy)
C ☐ Simple Compounding	D ☐ Injection Services (incl. vaccination)
E ☐ DAA	F ☐ Complex Compounding – Non-Sterile

Self-Audit Conducted By:		
Name	Position	Sections

Self-Audit Responses Reviewed by Licensee(s):		
Name	Position	Date:

VICTORIAN PHARMACY AUTHORITY (VPA)
SELF AUDIT FORM - PHARMACY

Improvement Actions	Action to be completed by	Date action completed

VICTORIAN PHARMACY AUTHORITY (VPA)
SELF AUDIT FORM - PHARMACY

A	Dispensing	Requirement met		
		Yes	No	N/A
A.1	If a non-PBS pharmacy, is there a PBS disclaimer notice?	☐	☐	☐
A.2	Is good dispensing practice being followed?	☐	☐	
A.3	Is the patient history reviewed on all occasions of dispensing?	☐	☐	
A.4	Is the expiry date checked during the selection of the medicine?	☐	☐	
A.5	Is there an extensive range of CA labels available to each dispensing station?	☐	☐	
A.6	Are there additional dispensing checks performed for drugs with special dosing regimens (e.g., methotrexate)?	☐	☐	
A.7	Are CA labels routinely applied to dispensed medicines except if deemed inappropriate by the dispensing pharmacist in a particular case?	☐	☐	
A.8	Is there a system in place to monitor the expiry date of medicines to prevent expired medicines being supplied?	☐	☐	
A.9	Is barcode scanning being routinely undertaken during the dispensing process? [The VPA encourages pharmacists to aim for 100% and to actively monitor scanning rates]	☐	☐	
A.10	Is distance dispensing carried out according to good pharmacy practice?	☐	☐	☐
A.11	Is SafeScript checked prior to dispensing a prescription for a high-risk medicine monitored by the system?	☐	☐	
A.12	Is the dispensing of a high-risk medicine prescriptions routinely recorded in the SafeScript system?	☐	☐	
A.13	Are prescriptions or copies of prescriptions kept with dispensed medicine until supply is made to the client?	☐	☐	
A.14	Is there a procedure to facilitate the final check of dispensed medicine against the original electronic prescription at the time of supply to the client?	☐	☐	

VICTORIAN PHARMACY AUTHORITY (VPA)
SELF AUDIT FORM - PHARMACY

B	Pharmacotherapy (Opioid Replacement Therapy (ORT)) Services	Requirement met		
		Yes	No	N/A
B.1	If the pharmacy provides pharmacotherapy to 20 or more persons per day, does: a) the dispensary include a bench or bench area of at least 0.6m^2 dedicated to the pharmacotherapy program that is not accessible to the public and provides for the secure storage of "in-use" S8 medicines? or	☐	☐	☐
	b) the pharmacy include a pharmacotherapy area located away from the dispensary that is air-conditioned, alarmed, fitted with a hot and cold water sink with drainer, fitted with a safe or drug cabinet to store S8 poisons, fitted with lockable storage for client records, and arranged to protect the privacy of pharmacotherapy clients?	☐	☐	☐
B.2	Are current editions of the Pharmacotherapy Policy and Guidelines available and readily accessible in the pharmacy?	☐	☐	
B.3	Is there a comprehensive pharmacy pharmacotherapy procedure manual readily available?	☐	☐	
B.4	Have all participating pharmacists signed a Program Certification form (Pharmacotherapy Policy Appendix 7)?	☐	☐	
B.5	Are methadone doses diluted prior to administration?	☐	☐	
B.6	Are methadone take-away doses diluted to 200ml with water, fitted with a child resistant cap and labelled in accordance with the APF?	☐	☐	
B.7	Are buprenorphine take-away doses labelled in accordance with the APF?	☐	☐	
B.8	Is client privacy maintained during daily dosing and handling and storage of administration books?	☐	☐	
B.9	Are all prescriptions current, and segregated from older ORT scripts?	☐	☐	
B.10	Are photos clear, certified, and suitable for the identification of clients?	☐	☐	
B.11	Are prescriptions and photos readily accessible when dosing?	☐	☐	
B.12	Is the date and time recorded for each dose administered or supplied?	☐	☐	
B.13	Is the attendance book signed by both the client and the pharmacist at the time each dose is administered or supplied?	☐	☐	
B.14	Is the total quantity of each S8 administered or supplied per day recorded in the S8 register daily?	☐	☐	
B.15	Is S8 register reconciled with the actual stock on hand on a regular basis?	☐	☐	
B.16	Is the working stock of methadone and buprenorphine kept secure and out of the sight and reach of clients?	☐	☐	
B.17	Is the working stock of methadone and buprenorphine returned to the S8 cabinet daily when dosing has been completed?	☐	☐	
B.18	Is hygiene maintained with re-usable takeaway bottles?			

VICTORIAN PHARMACY AUTHORITY (VPA)
SELF AUDIT FORM - PHARMACY

C	Simple compounding	Requirement met		
		Yes	No	N/A
C.1	Is compounding ONLY undertaken if an appropriate, suitable commercial product is unavailable?	☐	☐	
C.2	Is all compounding performed by a registered pharmacist or a trained technician under the supervision of a registered pharmacist?	☐	☐	
C.3	Does all compounding of medicines use formulae published in recognised and reputable references (e.g. APF) or using other formulae for which reliable information is available that confirms their quality, stability, safety, efficacy and rational	☐	☐	
C.4	Is a risk assessment conducted and documented before compounding a medicine as outlined in the current APF (*Compounding*)?	☐	☐	
C.5	Is the decision to prepare a compounded medicine(s) always justified as outlined in the current APF (*Compounding*)?	☐	☐	
C.6	Are the identified risk mitigation process/actions implemented prior to undertaking the compounding activity?	☐	☐	
C.7	Is compounding NOT undertaken in anticipation of receiving prescriptions, orders or requests unless they comply with Schedule 5, item 6A of the Therapeutic Goods Regulations?	☐	☐	
C.8	Are all ingredients used pharmaceutical grade?	☐	☐	
C.9	Is the water used for preparing non-sterile medicines of suitable quality (e.g. Purified Water BP/Ph Eur/USP or higher) at the point of use?	☐	☐	
C.10	Is water stored in clean, well closed containers that maintains the quality of the water and is labelled with expiry date and in-use expiry?	☐	☐	
C.11	Are all ingredients produced by manufacturers that have suitably approved quality assurance and quality control procedures (e.g. TGA Licence to Manufacture Therapeutic Goods or hold a certificate of GMP compliance or equivalent accreditation from a regulatory body equivalent to the TGA?	☐	☐	
C.12	Are all ingredients labelled, packaged, stored and handled in accordance with quality and safety requirements?	☐	☐	
C.13	Is evidence obtained to demonstrate that all ingredients meet pharmacopeial standards and are safe for use?	☐	☐	
C.14	Does the compounding record form include: a) Pharmacopeial name (if applicable) b) Formula and source c) Manufacturer's batch number and expiry dates of ingredients d) Method of preparation e) Calculations f) Weight/volume of ingredients measured g) Storage and expiry date assigned to the compounded medicine h) Details of container/closure used i) Duplicate of label used (including any CALs) j) Name(s), signature(s) and date of any supervised persons performing the activity k) Name, signature and date of supervising pharmacist	☐	☐	
C.15	Are quality control activities undertaken (e.g. visual appearance, calculations checked, measurements precise) prior to supply of the compounded medicine?	☐	☐	
C.16	Are errors, defects and complaints related to compounded medicines documented and investigated?	☐	☐	
C.17	Are suspected adverse effects reported to the TGA?	☐	☐	
C.18	Is there a recall procedure in place to enable complete and prompt recall of compounded medicines?	☐	☐	

VICTORIAN PHARMACY AUTHORITY (VPA)

SELF AUDIT FORM - PHARMACY

Alternatively use the self-audit tool: immunisation site readiness checklist codeveloped by DH and VPA: https://www.health.vic.gov.au/sites/default/files/2023-08/pharmacy-services-self-audit-tool-health-protection-august-2023.docx

D	Injection Services (including Vaccination)	Requirement met		
		Yes	No	N/A
D.1	Has VPA approval been obtained for a person who is *not* the owner or employee of the pharmacy business to provide vaccination services *(Refer to VP43 Application form*)?	☐	☐	☐
D.2	Is the pharmacy registered with the Department of Health (DH) as an immuniser service?	☐	☐	
D.3	Is the pharmacy registered as an immunisation provider on Australian Immunisation Register (AIR)?	☐	☐	
D.4	Are all immunisers working within the registered premises authorised to provide immunisations? Have all pharmacist immunisers completed a recognised immuniser program of study that is recognised by the Victorian Chief Health Officer and successfully completed any mandated training modules?	☐	☐	
D.5	Do all pharmacist immunisers hold current first aid and cardiopulmonary resuscitation (CPR) certificates? • First aid certificates issued within the last 3 years • CPR training renewed annually	☐	☐	
D.6	Is there a process to identify when training or First aid and CPR certificates are due for renewal?	☐	☐	
D.7	Is another person trained in First Aid and CPR present in pharmacy during vaccinations?	☐	☐	
D.8	Do pharmacist immunisers have access to AIR?	☐	☐	
D.9	Do pharmacist immunisers understand the scope of practice defined by the DH Approval, including inclusions and exclusions?	☐	☐	
D.10	Does the COVID-19 multi-dose vial vaccine 'preparation area' meet the following criteria:			
	a) An area away from direct patient contact, distraction and separate from areas that provide other pharmacy services at the same time; Note: preparation area may be in the dispensary or the administration area?	☐	☐	
	b) Adequate sanitisation facilities available?	☐	☐	
	c) Reconstituted COVID-19 multi-dose vials are marked or labelled with the date and time of access and expiration?	☐	☐	
	d) Vaccines from multi-dose vials (COVID-19 vaccines) are prepared in single use syringes and labelled for administration (vaccine name, batch, time and date of preparation and expiry)?	☐	☐	
	e) Visual reminders and cues to reduce the risk of errors	☐	☐	
	f) A cleaning and disinfection schedule in place?	☐	☐	
D.11	Is the vaccination administration room/area:			
	a) a suitable size (e.g., accommodates patients and accompanying persons or people with disability)?	☐	☐	
	b) visually private?	☐	☐	
	c) audibly private?	☐	☐	
	d) maintained at a comfortable temperature?	☐	☐	
	e) adequate sanitisation facilities available (e.g., sink with running hot and cold water or alcohol-based hand rub which is ARTG listed)?	☐	☐	

VICTORIAN PHARMACY AUTHORITY (VPA)
SELF AUDIT FORM - PHARMACY

D	Injection Services (including Vaccination)	Requirement met		
		Yes	No	N/A
D.12	Does the vaccination room/area have:			
	a) Bench, or suitable alternative, with an impervious surface?	☐	☐	
	b) Bed or suitable reclining chair?	☐	☐	
	c) Suitable hand washing facilities or alcohol sanitiser?	☐	☐	
	d) First aid equipment in a suitable and obvious location?	☐	☐	
	e) Anaphylaxis Kit in a suitable and obvious location?	☐	☐	
	f) Anaphylaxis Kit which is compliant with DH Victorian Pharmacist-Administered Vaccination program Guidelines?	☐	☐	
	g) Anaphylaxis response charts/guidelines on display?	☐	☐	
	h) Telephone within ready access in case of emergency?	☐	☐	
	i) Copy of Pharmacist's immuniser Certificate of Training on display?	☐	☐	
	j) Copy of Pharmacist's immunisers' First Aid Certificate on display?	☐	☐	
	k) Copy of Pharmacist's immunisers' CPR Certificate on display?	☐	☐	
	l) Emergency response protocol on display?	☐	☐	
	m) Sharps Kit?	☐	☐	
	n) Incident Record Book in a specific, suitable, and obvious location?	☐	☐	
	o) Patient observation area (for monitoring the patient for 15 min after vaccination or in accordance with professional guidelines)?	☐	☐	
D.13	Is there a process for safely disposing of unused vaccines?	☐	☐	
D.14	Are there procedures in place for cold chain management, including: • Checking delivery temperature trackers • Vaccines placed in refrigerator immediately following delivery • Stock control management • Backup plan for alternate storage if power failure • Twice daily minimum and maximum temperatures manually recorded • Cold chain breach protocol	☐	☐	
D.15	Are there procedures in place to ensure that pre- and post-immunisation assessment and administration of each vaccine is in accordance with the requirements in The Australian Immunisation Handbook and COVID-19 vaccines ATAGI recommendations?	☐	☐	
D.16	Is informed consent documented prior to immunisation?	☐	☐	
D.17	Is AIR checked prior to the administration of <u>every</u> vaccine?	☐	☐	
D.18	Is a Vaccination log/worksheet completed for each vaccination given? (e.g., Does it include all relevant information including name of administering pharmacist)?	☐	☐	
D.19	Are all vaccines administered recorded to the AIR (in a timely manner)?	☐	☐	
D.20	Are patients provided with immunisation information, receipt of vaccine and consumer information including potential side effects and what to do in the event of an adverse event?	☐	☐	

VICTORIAN PHARMACY AUTHORITY (VPA)
SELF AUDIT FORM - PHARMACY

E	Dose Administration Aids (DAA)	Requirement met		
		Yes	No	N/A
E.1	If the pharmacy regularly fills DAAs for 15 or more persons per week: a) Does the dispensary have a specific bench or bench area of at least 1m^2 dedicated to the filling of DAAs; and secure storage for dispensed medicines? or b) Does the pharmacy have an area for the filling of DAAs located away from the dispensary that is air-conditioned; alarmed and that has access to hand washing facilities; a 'patient history look up' computer terminal, DAA printing equipment; and lockable storage for dispensed medicines?	☐ ☐	☐ ☐	☐ ☐
E.2	Are dispensed medicines stored in containers of sufficient size to ensure effective segregation of each client's medicine?	☐	☐	
E.3	Are storage containers for dispensed medicines labelled with client's name?	☐	☐	
E.4	Are dispensed S8 Medicines used for 'virtual pill count' DAA systems e.g., *Webstercare Meds Pro* stored in a S8 cabinet when not in use?	☐	☐	
E.5	Are clients' medicines stored: a) in the dispensary? or b) in a lockable room or cupboard which is kept locked when not in use?	☐ ☐	☐ ☐	
E.6	Are there adequate procedures for: a) updating a client's profile b) collecting information for safe dispensing for patients not presenting at the pharmacy e.g. age / weight / medical conditions / allergies / lifestyle (self-medicating, ambulatory) etc c) providing clinical information to staff or resident e.g. counselling/trigger point notes d) identifying and processing DAAs which include drugs with specialised dosing regimens (e.g., methotrexate, alendronate) to ensure ongoing correct filling.?	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	
E.7	Are dose administration container filling and checking records (date, medication name, strength, dose, quantity, and initials of pharmacist) made and retained at pharmacy premises for at least 6 months?	☐	☐	
E.8	*Is DAA equipment (or machines) regularly cleaned?*	☐	☐	
E.9	Are dose administration containers labelled with: a) the patient's name? b) the pharmacy name, address, and telephone number? c) the drug name, strength, and directions for use? d) with APF cautionary and advisory labels OR is an alternative method of providing cautionary advisory information used e.g., providing clients with a medication profile?	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	
E.10	Is CAL 1 or 1a attached to the dose administration container where indicated by the APF? *(Note: This is a statutory requirement for the labelling of immediate containers. It is not satisfied by attaching a 1 or 1a CAL to a separate document such as a medication profile.)*	☐	☐	
E.11	Is the pharmacist in attendance (in separate DAA area)	☐	☐	
E.12	Is there evidence of training to undertake DAA packaging role: a) Dispensary Assistant(s) b) Other staff	☐ ☐	☐ ☐	

VICTORIAN PHARMACY AUTHORITY (VPA)
SELF AUDIT FORM - PHARMACY

Note: Refer to Simple compounding form for general requirements

F	Complex Compounding – Non-sterile	Requirement met		
		Yes	No	N/A
F.1	Is complex compounding undertaken in a dedicated compounding laboratory: a) that is lockable, or b) next to the main dispensary separated by a door?	☐	☐	
F.2	Is the laboratory fitted with hot and cold water and sink with drainer?	☐	☐	
F.3	Is the laboratory maintained and monitored at or below 25°C, at all times?	☐	☐	
F.4	Are all surfaces (benches, walls, doors, floors and ceiling) impermeable and cleanable?	☐	☐	
F.5	Prior to a decision to introduce hazardous materials, is a risk assessment performed? Note: Control measures should address: • the potential risk of cross contamination of equipment and whether separate distinguishable equipment is used and stored for each class of hazardous material if a validated cleaning/decontamination protocol is not used after each use. • Spills and accidental exposure	☐	☐	
F.6	Is there a suitable powder containment cabinet (for personal and environment protection) used for hazardous and potent substances?	☐	☐	
F.7	Is protective clothing (non-shedding gown or coat, disposable gloves and hair/beard covers) worn during compounding procedures?	☐	☐	
F.8	Is additional protective clothing worn when handling hazardous substances and potent substances such as hormones (e.g., disposable non-shedding gown, eye protection, respirator mask, shoe coverings)?	☐	☐	
F.9	Are baseline and regular periodic pathology tests performed on all staff handling hazardous materials? Note: the frequency and nature of the testing should be justified by undertaking an appropriate risk assessment.	☐	☐	
F.10	Is a risk assessment conducted and documented before compounding a medicine as outlined in the current APF (Compounding)?	☐	☐	
F.11	Are animal medicines compounded only on the prescription or the instructions of a veterinary practitioner, irrespective of poison schedule?	☐	☐	
F.12	Is batch preparation only undertaken in accordance with the Pharmacy Board of Australia Guidelines on compounding of medicines, e.g., for individual named patients for which multiple prescriptions have been received, and where a risk assessment has been undertaken?	☐	☐	
F.13	Is the decision to prepare a compounded medicine(s) always justified as outlined in the current APF (*Compounding*)?	☐	☐	
F.14	Are the identified risk mitigation process/actions implemented prior to undertaking the compounding activity?	☐	☐	
F.15	Are all ingredients produced by manufacturers that have suitably approved quality assurance and quality control procedures (e.g. TGA Licence to Manufacture Therapeutic Goods or hold a certificate of GMP compliance or equivalent accreditation from a regulatory body equivalent to the TGA?	☐	☐	
F.16	Is the water used for preparing non-sterile medicines of suitable quality (e.g. Purified Water BP/Ph Eur/USP or higher) at the point of use?	☐	☐	
F.17	Are all ingredients labelled, packaged, stored and handled in accordance with quality and safety requirements?	☐	☐	
F.18	Is evidence obtained to demonstrate that all ingredients meet pharmacopeial standards and are safe for use?	☐	☐	
F.19	Are manufacturer's batch numbers of all ingredients and other components recorded and readily assessable for recall and audit purposes?	☐	☐	
F.20	Are ingredients which are subject to testing, quarantined until the results are known and a decision taken on their status (release or destruction)?	☐	☐	
F.21	Does the compounding record form include: a) Pharmacopeial name (if applicable) b) Formula and source c) Manufacturer's batch number and expiry dates of ingredients d) Method of preparation e) Calculations f) Weight/volume of ingredients measured g) Storage and expiry date assigned to the compounded medicine h) Details of container/closure used i) Duplicate of label used (including any CALs) j) Name(s), signature(s) and date of any supervised persons performing the activity k) Name, signature and date of supervising pharmacist	☐	☐	

VICTORIAN PHARMACY AUTHORITY (VPA)
SELF AUDIT FORM - PHARMACY

F	Complex Compounding – Non-sterile	Requirement met		
		Yes	No	N/A
F.22	Is compounding carried out without distraction and free of external interruption?	☐	☐	
F.23	Is validation of complex compounding techniques performed? (e.g., activation of cannabis material)?			
F.24	Does a pharmacist initial or counter initial the compounding dispensing worksheet for each weighing/measuring and other significant step?	☐	☐	
F.25	Are expiry dates consistent with APF recommendations except where reliable stability data exist (never > 6 months)?	☐	☐	
F.26	Are compounded medicines recorded and labelled for the use of a specific patient and supplied directly to that patient or bona fide agent?	☐	☐	
F.27	Are compounding dispensing worksheets retained for three years from the date of dispensing?	☐	☐	
F.28	Are quality control activities undertaken (e.g. visual appearance, calculations checked, and measurements precise) prior to supply of the compounded medicine?	☐	☐	
F.29	Do compounded medicines meet the relevant TGA quality standards: • TGO 93 Standard for Medicinal Cannabis • TGO 95 Child-resistant packaging requirements for medicines • TGO 100 Microbial Standards for Medicines • TGO 110 Standard for Nicotine Vaping Products?	☐	☐	
F.30	Are quality assurance testing protocols (as defined by APF) for compounding medicines in place? Note: A risk-based selection criteria should be used to determine which compounded medicines are assayed, the frequency of assay and coverage of products compounded by each staff member?	☐	☐	
F.31	Are compounded medicines assayed by an accredited analytical laboratory?	☐	☐	
F.32	Are clients counselled on every occasion a compounded medicine is supplied including those delivered as part of a mail / online ordering system?	☐	☐	
F.33	Are there procedures to address: • Operator hygiene • Equipment maintenance and calibration • Equipment operation • Good compounding methods and techniques • Cleaning methods and cleaning records • Waste management • Quality assurance • Good compounding methods and techniques • Management of hazardous material spills and accidental exposure • Complaints • Recall	☐	☐	
F.34	Do cleaning records accurately reflect cleaning of the facility and equipment undertaken? Note: Records should include date and initials of operator performing the cleaning and the cleaning method used.	☐	☐	