VICTORIAN PHARMACY AUTHORITY
SELF AUDIT FORM

Pharmacy name and address:

.....

.....**P/code**.....

Date of audit.....

ACCESS TO PHARMACY PREMISES:

Guideline
Pharmacy premises must have at least one doorway opening from the premises to allow members of the public access to the premises from a street, public walkway, mall or public foyer**.**
Note: For the purpose of the guideline a mall or a public foyer in a multi tenanted building means an area inside the building that is open to the public but is not part of another tenancy or another business.

1. **Does the pharmacy have at least one doorway opening from the premises to allow members of the public to enter the pharmacy from a public place such as a street, public walkway, mall or public foyer?**

YES ☐ **NO** ☐

DISPENSARY:

Guideline
The dispensary is a private area dedicated to the dispensing of medicines and the secure storage of patients' records. Lighting, ventilation and temperature control are essential to maintaining the integrity of the medicines and for personal comfort. The dispensary is to be supplied with hot and cold running water and refrigeration, and provide a sufficient area for equipment and free working space.

2. **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?**

YES ☐ **NO** ☐

3. **Does the design of the dispensary prevent members of the public from entering the dispensary unnoticed by the pharmacist on duty?**

YES ☐ **NO** ☐

4. **Is the pharmacy arranged so that the dispensary is not used as a thoroughfare to access "back of house" areas?**

YES	NO
☐	☐

5. **Is access to medicines stored in the dispensary restricted to dispensary staff only?**

YES	NO
☐	☐

6. **Are all S4 medicines stored outside the dispensary kept in a locked facility?**

YES	NO
☐	☐

7. **Does the dispensary include a specific bench or bench area of at least 0.6 m^2 for the unpacking and sorting of dispensary orders received?**

YES	NO
☐	☐

8. **Does the dispensary include a sink with drainer with hot and cold running water?**

YES	NO
☐	☐

9. **Does the dispensary include a specific bench or bench area of at least 0.6 m^2 located near to the sink for the compounding or preparation of medicines and that also provides storage for compounding equipment?**

YES	NO
☐	☐

10. **Does the dispensary include a specific bench or bench area of at least 0.6 m^2 for dispensary clerical and research use?**

YES	NO
☐	☐

11. **If the pharmacy provides pharmacotherapy to 20 or more persons per day does the dispensary include a specific 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 alternatively does 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; is fitted with lockable storage for client records; and at which arrangements are in place to protect the privacy of pharmacotherapy clients?**

YES	NO	N/A
☐	☐	☐

12. **If the pharmacy regularly fills dose administration aids (DAAs) for 15 or more persons per week does the dispensary include a specific bench or bench area of at least 1 m^2 dedicated to the filling of DAAs; and secure storage for dispensed medicines; Or alternatively, Does the pharmacy include 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?**

YES	NO	N/A
☐	☐	☐

DISPENSING STATIONS

Guideline
A dispensary in a pharmacy is to include one dispensing station for each 150 prescriptions or part thereof dispensed on a typical day between 9am and 6pm.

A dispensing station is to include a dispensing bench of at least 0.6m² (e.g. 1000mm x 600 mm) equipped with a screen, a keyboard, a dedicated scanner, a dedicated printer for labels, a dedicated printer for repeat forms and adequate stationary. Each station must be convenient to a printer that prints Consumer Medicine Information (CMI). The CMI printer may be located at or away from the dispensing station and may service multiple dispensing stations.

If a dispensary assistant is involved with dispensing at a dispensing station, then an additional bench area of a least 0.6m², equipped with a keyboard and screen without label and printing capability, is recommended for the dispensing station. The bench area may be separate from, or an extension of the dispensing bench.

13. **Does the dispensary include one dispensing station for each 150 prescriptions or part thereof dispensed on a typical day between 9 am and 6 pm?**
Note for the purpose of this calculation one ORT administration is equivalent to one prescription.

YES	NO
☐	☐

14. **Does each dispensing station include a dispensing bench of at least 0.6 m^2 (e.g. 1000 mm x 600 mm) equipped with a screen, a keyboard, a dedicated scanner, a dedicated printer for labels, a dedicated printer for repeat forms and adequate stationery?**

YES	NO
☐	☐

15. **Is each dispensing station convenient to a printer that prints Consumer Medicine Information (CMI)?** *(The CMI printer may serve multiple dispensing stations).*

YES	NO
☐	☐

COUNSELLING AREA

Guideline

A distinct area (which may be part of the professional service area) is required that permits the pharmacist to discuss any matter with a member of the public on a private and confidential basis. The area must be positioned such that any conversations are out of the hearing of other persons. Care must also be exercised in ensuring that third parties do not see a patient's medicines, the packaging of which is indicative of the medicines' identity and potentially its purposes.

Dedicated prescription reception and counselling points fitted with opaque privacy screens that rise to at least 600 mm above the bench to form a booth or that are otherwise arranged or located to provide privacy are required. There should be as many counselling points as there are dispensing stations. They should be designed to encourage routine use for all prescription transactions. A password-protected screen and keyboard is recommended in each.

A separate room or office may also be used for the above purposes and for the provision of extended services such as disease screening, prolonged consultations or structured patient programs that, to be effective require privacy and freedom from interruptions. Pharmacists should determine if a level of privacy, as achieved in a counselling room, is required to undertake the more extensive professional activities, compared with the level of privacy that can be achieved in the Professional Service Area for the more routine patient interactions.

Note: A dedicated counselling point is not required for dispensing stations situated in an area used to pack dose administration aids and which is dedicated to the dispensing of prescriptions for packing into dose administration aids.

16. **Is there a dedicated prescriptions reception and counselling point for each dispensing station used to dispense prescriptions for clients who attend the pharmacy to collect their medicine?**

YES	NO
☐	☐

17. **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?**

YES	NO
☐	☐

PROFESSIONAL SERVICE AREA

Guideline
To reflect the professional nature of a pharmacist's dealings with the public, a professional service area is required. It is a distinct area distinguished by décor and signs stating professional service area. The area is used solely for the purpose of displaying and storing products for therapeutic use and information about them.
Note: The professional service area should be situated and arranged to allow supervision by the pharmacist(s) on duty.

18. Is there a professional service area in the public part of the pharmacy?

YES	NO
☐	☐

19. Is the professional service area distinguished by décor and / or signs?

YES	NO
☐	☐

20. Is the professional service area be used solely for the display and storage of products for therapeutic use and information about them?

YES	NO
☐	☐

SCHEDULE 8 POISONS – STORAGE and RECORDS

Guideline
Schedule 8 poisons (Controlled Drugs) are to be stored in accordance with the Drugs, Poisons and Controlled Substances Regulations 2006.

The increased use of Schedule 8 poisons (including substitution therapies) and bulkier packaging indicate the need for installing safes or lockers that are large enough to store all S8 poisons on hand (taking into account future needs) and to facilitate accurate selection of the medicines from the safe or locker.

Specifications about drug safes or lockers are available from locksmiths and safe manufacturers. The safe or locker must meet at least the minimum standards prescribed under the Drugs, Poisons and Controlled Substances Regulations 2006 and installed in accordance with the Regulations to ensure that it cannot be removed easily.

Bulk quantities of "in use" substitution therapies that are administered to patients attending the pharmacy need to be located so that they are inaccessible to, and preferably out of sight of, the patient.

Keys to the Schedule 8 poisons safe must not be left on the premises overnight, unless they are stored in a safe of at least equivalent security to the Schedule 8 safe and to which pharmacists have exclusive access. In most cases, this will be a safe fitted with a combination lock or a keypad, the codes to which will be limited to pharmacists.

Guide to the Drugs, Poisons & Controlled Substances Regulation 2006: [re Regulation 35(1)(f)] Expert advice received by the Department indicates that the requirement to be securely attached is satisfied by –

a) HARD CORE WALL: The cabinet to be secured by use of four (4) Loxin or Dyna Bolts, each 10mm by 50mm minimum.

b) STUD AND PLASTER OR HOLLOW BLOCK: The cabinet to be secured by use of four (4) 10mm coach bolts through wall and through 3mm mild steel backing plate. This backing plate must, at minimum, be the same size as the back of the drug cabinet.

21. Is the dispensary equipped with safes or drug cabinets large enough to store all S8 poisons in a way that facilitates the accurate selection of medicines?

YES ☐ NO ☐

22. Is each drug cabinet attached in accordance with the Guide to the Drugs, Poisons & Controlled Substances Regulation 2006?

YES ☐ NO ☐

23. Is the S8 safe key kept on the person of a pharmacist or otherwise secured eg in a key safe (may have combination lock) which provides security equivalent to that of the S8 safe?

YES ☐ NO ☐

24. Are transactions involving Controlled Drugs (Schedule 8 poisons) recorded in the Controlled Drug Register as soon as practicable after completing the transaction?

YES ☐ NO ☐

25. Is the true balance of a Controlled Drug recorded in the Register (i.e. negative balances are not recorded in the case of partial supply)?

YES ☐ NO ☐

26. Is the Controlled Drug Register regularly reconciled with the actual stock on hand of Controlled Drugs?

YES ☐ NO ☐

CONTROLLED TEMPERATURE STORAGE

Guideline
Pharmacies and pharmacy departments are required to provide facilities in which medicines are stored at temperatures within their recommended temperature range.
Temperatures in a pharmacy or pharmacy department should not exceed 25ºC; to this end, thermostatically controlled air conditioning or cooling by other means is necessary unless the premises are so situated or constructed as not to allow this temperature to be exceeded. Air conditioners should be set to maintain temperatures not exceeding 25ºC during periods when the pharmacy is not open for business.
Refrigerators used to store medicines should be dedicated to this purpose. A continuously reading thermometer is required with the sensor (known as a data logger) connected to the computer (or functionally similar arrangements) to alert staff to any malfunction when the premises are unoccupied and provide sufficient information to allow the effect of the malfunction on the integrity of the medicines to be assessed .

27. **Are all medicine storage areas serviced by a thermostatically controlled air-conditioner that maintains storage temperatures so that the temperature does not exceed 25ºC at all times?**

YES ☐ NO ☐

28. **Is dispensary equipped with a refrigerator dedicated to the storage of medicines?**

YES ☐ NO ☐

29. **Is the refrigerator dedicated to the storage of medicines fitted with a continuously reading thermometer connected to a computer (or functionally similar arrangement such as a data logger) to allow the effect of any malfunction on the integrity of the medicines to be assessed?**

YES ☐ NO ☐

EQUIPMENT

30. **Is the dispensary equipped with a range of reference texts in accordance with the Pharmacy Board of Australia's Guidelines?**
(Refer: http://www.pharmacyboard.gov.au/Codes-Guidelines.aspx)

YES ☐ NO ☐

31. **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?**

YES ☐ NO ☐

32. Is the dispensary equipped with an adequate range of accurately calibrated measures eg 10ml, 50ml & 200ml?

YES ☐ NO ☐

SECURITY

Guideline
Pharmacies are required to be constructed to prevent, as far as is reasonable, unauthorised access through doors, windows, walls and ceilings.

33. Is the pharmacy fitted with an electronic intruder alarm fitted that conforms to Australian Standard 2201: Intruder Alarm Systems?

YES ☐ NO ☐

34. Does the electronic alarm cover the perimeter of the pharmacy as well as all areas where medicines are kept including the dispensary, Schedule 8 cabinet or safe, rooms used to store dispensed medicine for packing into dose administration aids, the professional service area and storerooms?

YES ☐ NO ☐

35. Is the electronic alarm monitored by central agency on a 24 hours 7 days a week basis?

YES ☐ NO ☐

36. Does the central agency hold a security firm licence?

YES ☐ NO ☐

37. Does the central agency have facilities that conform to Australian Standard 2201.2 Intruder Alarm Systems – Monitoring Centres Grade 1, 2 or 3?

YES ☐ NO ☐

38. If the building permit permits, is each perimeter door to the pharmacy fitted with a lock that prevents the door from being opened by hand from the inside when the premises are not lawfully occupied, OR if such locks are not permitted, are other measures in place to prevent entry through roofs or ceilings such as floor to roof walls or ceiling space alarm sensors?

YES ☐ NO ☐

39. 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?

YES ☐ NO ☐ N/A ☐

40. Are perimeter windows to secluded or non-public areas fitted with bars or security grilles?

YES ☐ NO ☐ N/A ☐

41. Are skylights fitted with bars or security grilles?

YES ☐ NO ☐ N/A ☐

CASH & WRAP OR CHECKOUT COUNTERS

Pharmacy Regulation Act 2010 Schedule para 9(h):
Adequate arrangements are to be in place to ensure that the identity of a medicine being supplied or dispensed to a client of a pharmacy cannot be known by another person present in the pharmacy who is not a person carrying on the pharmacy business or a member of staff of the business

42. Are 'cash and wrap' or 'checkout' counters arranged to ensure that the identity of a medicine being paid for by the client cannot be known by another client at the counter?

YES ☐ NO ☐

43. Are arrangements in place to ensure the identity of dispensed medicine being taken to the cash and wrap counter cannot be known by other clients in the pharmacy?

YES ☐ NO ☐

USE OF DISPENSARY

Guideline
The dispensary is a private area dedicated to the dispensing of medicines and the secure storage of patients' records.

POS data entry stations, non-dispensary clerical work areas and staff areas are to be located outside of the dispensary.

44. Are all non-dispensary tasks performed outside the dispensary (e.g. POS data entry, storage of non-dispensary stock, storage of display materials)?

YES ☐ **NO** ☐

45. Do non-dispensary staff members store their personal belongings and take meal and tea breaks outside the dispensary on all occasions?

YES ☐ **NO** ☐

DISPLAY OF NAMES

Guideline
The public is entitled to know the names of the pharmacists with whom they are dealing in a professional capacity.
The name or names of the proprietor of a pharmacy, natural or corporate, must be displayed on a sign placed at all the entrances to the pharmacy where the public has access so as to be clearly visible from the street or public thoroughfare. The font size should be at least 72 points.
The name of the pharmacist who is regularly and usually in charge of the pharmacy or pharmacy department and the name or names of other pharmacists on duty are to be displayed in the professional service area or the place where medicines are usually collected by the public.
Note: The name of the pharmacist regularly and usually in charge of the pharmacy ('PRUIC") should be displayed at all times including times when that person is not in attendance or on duty at the pharmacy. Signage at the pharmacy should indicate if the PRUIC is on duty.

46. Is the proprietor's name or names clearly displayed at all public entrances to the pharmacy?

YES ☐ **NO** ☐

47. Is the name of the pharmacist who is regularly and usually in charge of the pharmacy clearly displayed in the professional services area of the pharmacy at all times?

YES ☐ **NO** ☐

48. Is the name of all the pharmacist(s) on duty clearly displayed in the professional services area of the pharmacy?

YES	NO
☐	☐

DISPENSING WORKLOAD

Guideline
As a benchmark, not less than one full-time equivalent pharmacist dispensing an average of 150 prescriptions over a 9.00am to 6.00pm day, and pro rata on weekends and public holidays, is regarded as the minimum staffing level. Attention should be paid to predictable spikes in activity during specific times, days or months. Sustainable workload may also be affected by other factors such as dispensing technologies, staff familiarity with systems and other non-dispensing responsibilities.
The preparation of each take-away dose take-away of methadone or buprenorphine and each administration of either drug is counted as being the equivalent of one prescription.
An individual pharmacist must not supervise more than two dispensary assistants or dispensary technicians engaged in the selection, processing and labelling of prescription medicines at a time. Other trained dispensary assistants or dispensary technicians can be engaged in duties that do not require direct supervision outside of this ratio (e.g. in dispensary stock control or preparing dose administration containers).
If dispensing levels are in the range of 150-200 prescriptions per day, a trained dispensary assistant and/or an intern pharmacist may assist the pharmacist. If the workload is in the range of 200 to 220 prescriptions daily, a second dispensary assistant may be used but above this workload, a second pharmacist will be necessary for at least part of the day.
The Authority acknowledges that a pharmacist may be required to dispense above this rate in unforeseen circumstances such as staff shortage due to sudden illness. The Authority recognises that in such circumstances the pharmacist can take effective short term measures to allow him or her to deal with the workload and meet his or her professional obligations.

49. Is the pharmacy staffed in accordance with the Victorian Pharmacy Authority's Guidelines?

YES	NO
☐	☐

PRACTICE – General

50. Is there a cleaning roster with 'sign off' provision in place and used to ensure the pharmacy is maintained in a hygienic and orderly manner?

YES	NO
☐	☐

51. Is there an extensive range of CA labels available to each dispensing station?

YES	NO
☐	☐

52. Are CA labels routinely applied to dispensed medicines except if deemed inappropriate by the dispensing pharmacist in a particular case?

YES ☐ NO ☐

53. Are Incident Records made and retained for three years in a dedicated file?

YES ☐ NO ☐

54. Is there a formal procedure in place to facilitate reliable inter-staff professional communications?

YES ☐ NO ☐

55. Is prescription counselling offered on all occasions of dispensing?

YES ☐ NO ☐

56. Is the patient history reviewed on all occasions of dispensing?

YES ☐ NO ☐

57. Does the pharmacist on duty routinely monitor the sale of Pharmacy Medicines by non-pharmacist members of staff?

YES ☐ NO ☐

58. Are S3 medicines displayed or stored for sale to prevent ready self-selection by the public, and in a way that does not promote or draw undue attention to them?

YES ☐ NO ☐

59. For S3 medicines containing codeine, is only one shelf-facing of the smallest commercial package of each product displayed (and all other stocks kept out of the public's view)?

YES ☐ NO ☐

60. For S3 medicines containing pseudoephedrine is the quantity of stock displayed for sale kept to no more than that sufficient for 1 weeks sales from the pharmacy?

YES ☐ NO ☐

61. **For S3 medicines containing pseudoephedrine is reserve stock kept out of public view?**

YES	NO
☐	☐

62. **Does the pharmacist take all reasonable steps to ensure a therapeutic need exists before supplying a S3 poison?**

YES	NO
☐	☐

63. **Is only one package of an S3 poison supplied at a time (unless there are exceptional circumstances and the supply is documented)?**

YES	NO
☐	☐

64. **Are returned medicines including those returned from nursing homes and those in dose administration aids stored in a secure manner and disposed of in RUM bins regularly?**

YES	NO
☐	☐

65. **Are arrangements in place to ensure that client information cannot be obtained by others from discarded documents?**

YES	NO
☐	☐

PRACTICE – Opioid Replacement Therapy

66. **Are current editions of the Pharmacotherapy Policy and Guidelines available and readily accessible in the pharmacy**

YES	NO
☐	☐

67. **Is there a comprehensive pharmacy pharmacotherapy procedure manual readily available?**

YES	NO
☐	☐

68. **Have all participating pharmacists signed a Program Certification form (Pharmacotherapy Policy Appendix 5)?**

YES	NO
☐	☐

69. **Are Methadone doses diluted prior to administration?**

YES	NO

☐ ☐

70. Are Methadone take–away doses diluted to 200ml with water, fitted with a child resistant cap and labelled in accordance with the APF?

YES ☐ NO ☐

71. Are Buprenorphine take-away doses labelled in accordance with the APF?

YES ☐ NO ☐

72. Is client privacy maintained during daily dosing and handling and storage of administration books?

YES ☐ NO ☐

73. Are all prescriptions current?

YES ☐ NO ☐

74. Are photos clear, certified and suitable for the identification of clients?

YES ☐ NO ☐

75. Are prescriptions and photos readily accessible when dosing?

YES ☐ NO ☐

76. Is the date and time recorded for each dose administered or supplied?

YES ☐ NO ☐

77. Is the attendance book signed by both the client and the pharmacist at the time each dose is administered or supplied?

YES ☐ NO ☐

78. Is the total quantity of each S8 administered or supplied per day recorded in the S8 Register daily?

YES ☐ NO ☐

79. Is S8 Register reconciled with the actual stock on hand on a regular basis?

YES ☐ NO ☐

80. Is the working stock of methadone and buprenorphine kept secure and out of the sight and reach of clients?

YES ☐ NO ☐

81. Is the working stock of methadone and buprenorphine returned to the S8 cabinet daily when dosing has been completed?

YES ☐ NO ☐

PRACTICE – Dose Administration Aids

82. Are dispensed medicines stored in containers of sufficient size to ensure effective segregation of each client's medicine?

YES ☐ NO ☐

83. Are storage containers for dispensed medicines labelled with client's name?

YES ☐ NO ☐

84. 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?

YES ☐ NO ☐ N/A ☐

85. Are clients' medicines stored in the dispensary OR in a lockable room or cupboard which is kept locked when not in use?

YES ☐ NO ☐

86. Are dose administration containers labelled with the patient's name?

YES ☐ NO ☐

87. Are dose administration containers labelled with the pharmacy name, address and telephone number?

YES ☐ NO ☐

88. Are dose administration containers labelled with the drug name, strength and directions for use?

YES ☐ NO ☐

89. **Are dose administration containers labelled 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?**

YES ☐ NO ☐

90. **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.)

YES ☐ NO ☐

91. **Is client information e.g. age / weight / medical conditions / allergies / lifestyle (self-medicating, ambulatory etc) routinely collected and recorded for clients obtaining medicines in dose administration aids?** (Note: This is particularly relevant for clients who do not attend the pharmacy).

YES ☐ NO ☐

92. **Are dose administration containers for patients requiring hazardous drugs (e.g. cytotoxic, warfarin) or drugs with special dose regimes (e.g. methotrexate, alendronate) identified or quarantined to ensure correct ongoing handling and filling?**

YES ☐ NO ☐

93. **Are dose administration container filling records (date, medication name, strength, dose, quantity and initials of pharmacist) made and retained at pharmacy premises for at least 6 months?**

YES ☐ NO ☐

PRACTICE – Compounding

94. **Is compounding undertaken in a dedicated room (laboratory) that is lockable or immediately next to the main dispensary?**

YES ☐ NO ☐

95. **Are all surfaces cleanable by washing?**

YES ☐ NO ☐

96. **Are dated and initialled cleaning logs maintained?**

YES ☐ NO ☐

97. Is the laboratory maintained at or below 25 degrees Celsius at all times?

YES ☐ NO ☐

98. Are the scales approved and of a sensitivity appropriate to the range of work being undertaken?

YES ☐ NO ☐

99. Are the scales tested at specified intervals and calibration logs maintained?

YES ☐ NO ☐

100. Is there an adequate range of accurately calibrated metric measures?

YES ☐ NO ☐

101. Is the compounding room fitted with a hot and cold water sink with drainer?

YES ☐ NO ☐

102. Is protective clothing (laboratory coat, disposable gloves and hair covers) worn during compounding procedures?

YES ☐ NO ☐

103. Is additional protective clothing worn for handling hazardous substances and potent substances such as hormones (e.g. eye protection, respirator mask, shoe coverings).

YES ☐ NO ☐

104. Is a powder containment cabinet (that meets AS 2252.1 – 2002: Biological Safety Cabinets (Class 1) for personal and environment protection) used for hazardous and potent substances?

YES ☐ NO ☐

105. Is compounding carried out without distraction and free of external interruption?

YES ☐ NO ☐

106. Is a risk assessment to assess the potential risks to staff & consumers conducted before compounding a medicine as outlined in APF 22 (Extemporaneous Dispensing)?

YES ☐ NO ☐

107. Are compounded medicines recorded and labelled for the use of a specific patient and supplied directly to that patient or bona fide agent OR recorded and labelled for the use of a doctor/veterinarian but not for the purpose of on-supply?

YES ☐ NO ☐

108. Are animal medicines compounded only on the prescription or the instructions of a veterinary practitioner, irrespective of poison schedule?

YES ☐ NO ☐

109. Are clients counselled on every occasion a compounded medicine is supplied including those delivered as part of a mail / online ordering system?

YES ☐ NO ☐

110. Are batch quantities of products prepared only in limited quantities based on the history of prescriptions received for that product, and taking into account the shelf life assigned to the product?

YES ☐ NO ☐

111. Is there a Master formula book/database for commonly compounded medicines?

YES ☐ NO ☐

112. Is an extemporaneous dispensing worksheet completed for each prescription compounded e.g. APF extemporaneous dispensing form template?

YES ☐ NO ☐

113. Is the expiry date of the finished product shown on the worksheet (may be included by means of a duplicate label attached placed on the worksheet)?

YES ☐ NO ☐

114. Does a pharmacist initial or counter initial the extemporaneous dispensing worksheet for each weighing/measuring and other significant step?

YES	NO
☐	☐

115. Is each extemporaneous dispensing worksheet signed-off and dated by the supervising or compounding pharmacist?

YES	NO
☐	☐

116. Are extemporaneous dispensing worksheets retained for three years from the date of dispensing?

YES	NO
☐	☐

117. Are storage conditions and the expiry date shown on labels of dispensed compounded preparations?

YES	NO
☐	☐

118. Is a consolidated incident/complaints record kept for three years in accordance with Pharmacy Board of Australia Guidelines for Dispensing of Medicines: Incident Records?

YES	NO
☐	☐

119. Is there a written Procedure Manual which includes:

a) Cleaning procedures for rooms and equipment
b) Operator hygiene standards
c) Waste disposal procedure ensuring safety of staff &environment
d) Operator exclusion policy (e.g. pregnancy, wounds)
e) Baseline and regular pathology monitoring of all staff handling hazardous material.
f) Procedure for product recall?

YES	NO
☐	☐

120. Are relevant compounding references readily available to compounding staff e.g. APF, Martindale, MSDS (material safety data sheet) register?

YES	NO
☐	☐

121. **Is a written job description maintained for each compounding dispensary assistant (detailing responsibilities & limitations)?**

YES ☐ NO ☐

122. **Are all staff who carry out compounding either pharmacists or trained dispensary assistants/interns/pharmacy students who work under the direct supervision of a pharmacist?**

YES ☐ NO ☐

123. **Are baseline and regular periodic pathology tests performed on all staff handling hazardous materials?**

YES ☐ NO ☐

124. **Are raw materials (including water) obtained from:**

i. **an Australian-licensed supplier; or**
ii. **a supplier in a country listed in Appendix B of the most recent edition of the Australian Regulatory Guidelines: Good Manufacturing Practice (GMP): Clearance for Overseas Manufacturers", published by the Therapeutic Goods Administration [see: www.tga.gov.au/pdf/manf-overseas-medicines-gmp-clearance-17.pdf]; or**
iii. **another supplier, provided that the compounding pharmacist has obtained a certificate of analysis from a laboratory accredited by the National Association of Testing Authorities (NATA) for each batch of raw material obtained from that supplier.**

YES ☐ NO ☐

125. **Do raw materials (including water) comply with pharmacopoeial standards and have validated expiry dates.**

YES ☐ NO ☐

126. **Is there a quarantine area and procedure for raw materials being held from use.**

YES ☐ NO ☐

127. **Are expiry dates consistent with APF recommendations except where reliable stability data exist (never > 6 months).**

YES ☐ NO ☐

128. Are frequently compounded medicines assayed by a competent analytical laboratory at least annually.

YES	NO
☐	☐

129. Is there a documented product recall procedure.

YES	NO
☐	☐

Certification:

I, ……..(Insert full name)

being the licensee or the pharmacist usually and regularly in charge of the pharmacy the pharmacy business at

…….(Insert pharmacy address)

hereby certify that the above information is true and correct at the date of signing.

…….Signature ……/……./……..(Date)