Pharmacy Gap Analysis – Non-Sterile Compounding

Listed below are the base level requirements for non-sterile compounding, as laid out in the NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations. Through the completion of a Risk Assessment, if you have identified that your pharmacy falls into the category of Level B or Level C Non-Sterile Compounding, please complete the additional page that is applicable to either Level B or C. For a thorough understanding of the requirements, the NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations and the NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations Guidance Document must be read in full.

Please complete the gap analysis by marking 1, 2 or 3 for each point listed below
Legend:
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3 – We need help to be compliant

5.1 Personnel
All personnel are responsible for knowing and performing their roles and responsibilities in accordance with the NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations and regulatory requirements

___ The Pharmacy Manager is responsible for the development, organization and supervision of all activities related to the compounding of non-sterile preparations

___ The non-sterile compounding supervisor is responsible for developing, organizing and overseeing all activities related to the compounding of non-sterile preparations

___ The non-sterile compounding supervisor must ensure that a quality assurance program is in place and that all requirements outlined in the NAPRA Model Standards are followed appropriately

___ Regulated pharmacy personnel must comply with established policies and procedures and ensure that all compounding standards and Model Standards of Practice for Canadian Pharmacists have been met

___ Non-regulated pharmacy personnel can only perform activities under appropriate supervision once appropriate training has been completed and documented

5.2 – Training and Skills Assessment

___ A training program must be in place for all compounding personnel and a record of training must be kept

___ A skills assessment program must be established, administered and documented for all personnel involved in non-sterile compounding. A record must be kept of assessment results and any corrective action taken
Cleaning personnel must be properly trained so they are aware of the importance of cleaning activities required to prevent cross contamination.

5.3 – Policies and Procedures

Policies and procedures for all activities related to non-sterile compounding must be established.

Policies and procedures must be reviewed at least every 3 years, or more frequently if there is a change in practice or standards. All changes must be documented.

5.4 – Facilities and Equipment

Facilities -

Compounding must be performed in a separate, specifically designated space.

Space must be large enough for compounding personnel to work comfortably and safely; must be room to store all equipment and products in an orderly manner and in clean and secure surroundings, away from high traffic areas.

Components, equipment and containers must be stored off the floor, allowing for appropriate cleaning and preventing contamination.

Space must be conducive to necessary cleaning, and must be maintained in sanitary condition and good repair.

Space must be adequately lit for performing compounding activities.

Clean water supply, with hot and cold running water must be available in or close to compounding area.

Heating, ventilation and air conditioning systems must be controlled to avoid decomposition and contamination of chemicals, to maintain the quality of products and to ensure the safety and comfort of compounding personnel.

Work surfaces and furniture, as well as floor and wall surfaces, must be designed to facilitate repeated cleaning.

Equipment -

Must be appropriate for the type of preparations that are going to be compounded.

Must not negatively affect the purity or quality of the preparation being compounded.

Must be cleaned well after each use, and regularly as recommended by the manufacturer, to disinfect and prevent cross contamination.

Log must be kept, recording each cleaning session.

Must be routinely inspected and calibrated, if applicable, at appropriate intervals as recommended by the manufacturer, or at least once a year if no manufacturer recommendations.

Must meet any requirements established by the regulatory authority (e.g. fridges and balances, etc.)

Records of calibration dates for equipment and instruments must be maintained.
6 – Product and Preparation Requirements

- Beyond use dates (BUD) must be determined after consulting the manufacturer’s documentation and literature of the stability, compatibility and degradation of ingredients.
- Preparations must be monitored for signs of instability and/or degradation.
- Master formulation record must be developed for each non-sterile compound.
- Master formulation records must be readily accessible to compounding personnel and include all necessary compounding information with rationale and supporting references.
- A compounding record must be kept for each individual prescription and for non-sterile preparations made in batches (bulk compounding).
- Ingredients used must be obtained from recognizable and reliable sources and must be pure and of good quality (traceable).
- Ingredients that have been recalled or withdrawn from the market for safety reasons must not be used and must be stored separately in a quarantined area.
- Ingredients must be stored under conditions that will preserve their quality and purity. Current safety data sheets must be readily accessible for all ingredients.
- Purified water or water of equivalent or superior quality must be used whenever the formula specifies water as an ingredient.
- Verification must be performed at each stage of the compounding process with final verification to take place prior to the preparation being dispensed.
- A policy for labelling and packaging must be established that is consistent with the requirements of SCPP and applicable federal regulations.
- The label and supplementary label(s) must provide all information consistent with SCPP requirements and include information for proper use of the compounded preparation by the patient or for safe administration by a third party.
- Packaging must be appropriate to maintain the integrity of the compounded preparation.
- A storage procedure must be established that is also consistent with requirements of SCPP.
- Policies for transport and delivery must be in place and meet provincial and federal regulatory requirements as well as address any special precautions required.
- Procedures for recall of products must include documentation to ensure traceability of all ingredients included in non-sterile compounded preparations.
- An event report must be completed for any incident or accident involved a compounded non-sterile preparation.

Personnel -

- Must follow all pertinent policies and procedures and behave in a professional manner.
- Must perform proper hand hygiene.
- Must wear clean lab coat, or disposable gown, that is reserved for compounding.
- Must wear/use any other personal protective equipment or equipment indicated on the master formulation record.
- Must not consume food or drinks or chew gum in the compounding area.
- Must take any other reasonable measures to prevent cross contamination and to protect themselves from chemical exposure.
7 – Quality Assurance

- A Quality Assurance Program must be developed and implemented to ensure the clear definition, application and verification of all activities affecting the quality of the final product and the protection of personnel
- Equipment must be certified at installation and at regular intervals, according to the manufacturer’s recommendations
- Temperature readings must be taken at regular intervals to ensure the integrity of products stored in refrigerators, in freezers or at room temperature
- Compounding personnel must be trained, certified and reassessed at regular intervals to ensure maintenance of competency
- Compliance with compounding procedures must be monitored
- Documentation must be verified, signed and retained as per requirements of SCPP
- Non-compliance and corrective actions must be documented
Level B Non-Sterile Compounding
(Complex compounds, as defined in USP General Chapter 795)

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Requirements in addition to base level requirements:

8.2 – Level B Requirements
Facilities –
_____ Separate, well ventilated room that provides greater protection from cross-contamination than Level A requirements
_____ Room must be large enough to accommodate storage of all appropriate equipment and provide an environment conducive to working comfortably with limited interruptions
_____ May require a ventilated containment device when certain powders, aromatic products or occasional hazardous products are being compounded
Level C Non-Sterile Compounding
(Compounds involving; hazardous drugs as classified by NIOSH as Group 1 drugs; hazardous materials as classified by WHMIS as representing a health hazard such as those products that are very irritating to the respiratory tract, the skin or the mucous membranes; NIOSH Group 2 or 3 drugs for which large quantities of API’s are used routinely)

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Requirements in addition to base level requirements:

9 – Requirements for Hazardous Preparations
   ____ Completion of a risk assessment, to be reviewed every 12 months

9.1 - Facilities for Handling Hazardous Products (Level C)
   ____ Separate room that is well ventilated with appropriate air exchanges and undernegative pressure
   ____ Appropriate containment device to be installed for materials to be compounded
   ____ Must be constructed to minimize risk of exposure to compounding personnel and other pharmacy staff
Compounding Room –
   ____ Must be ventilated through HEPA filtration, have appropriate air exchanges and have negative pressure relatives to surrounding rooms
   ____ Must contain an eyewash station and any other emergency or safety equipment required
   ____ Must be constructed with smooth, impermeable surface to promote adequate cleaning and decontamination
Storage –
   ____ Hazardous products must be stored in a room with appropriate ventilation
   ____ Areas for storing and preparing hazardous products must be identified with appropriate signage

9.2 - Equipment for Handling Hazardous Products
   ____ A Containment Primary Engineering Control (C-PEC) that provides appropriate personal and environmental protection must be installed and maintained
   ____ All reusable equipment and devices must be adequately deactivated, decontaminated and cleaned
Personal protective equipment approved for the compounding of hazardous non-sterile preparations must be worn during compounding activities

9.3 - Deactivating, Decontaminating and Cleaning

- Cleaning must also eliminate chemical contamination, specifically by deactivating, decontaminating and cleaning the premises and equipment
- Cleaning personnel must comply with the pharmacy’s hand hygiene and garbing procedure for handling hazardous products
- The work surface of the C-PEC must be deactivated, decontaminated and cleaned before starting the compounding of a different preparation

9.4 - Incident and Accident Management

- Policies and procedures are in place and followed for cases of accidental exposure of personnel to hazardous products
- Personnel receive training to prevent spills, how to appropriately clean up spills and the proper use of a spill kit
- All incidents and accidents are documented and followed up on to prevent recurrence

9.5 - Hazardous Waste Management

- Procedures are in place for the destruction and/or disposal of pharmaceutical waste in compliance with environmental protection legislation
- Personnel involved in the management of hazardous product waste receive appropriate training and have access to all necessary personal protective equipment and cleaning supplies

9.6 – Verification of Controlled Rooms and the C-PEC

- The controlled room and C-PEC are examined and certified every 6 months according to manufacturer’s recommendations, as appropriate
- Manufacturer’s factory-issued certificates for all HEPA filters and C-PECs must be retained for the service life of the equipment
- An environmental verification program has been established to ensure safety standards
- All completed documentation concerning components of testing of controlled rooms and equipment for hazardous product contamination must be filed and retained with other compounding records