SASKATCHEWAN
COLLEGE OF PHARMACY
PROFESSIONALS

Pre-Opening Non-Hazardous Non-Sterile (Level A & B) Compounding Evaluation Supplementary Inspection Checklist

Pharmacy Name: **Permit Number:**

Pharmacy Address:

Pharmacy Phone: **Pharmacy Fax:**

Pharmacy Manager: **Field Officer:**

Proposed Opening Date: **Date:**

	S = Satisfactory	U = Unsatisfactory
1. Personnel:	**S**	**U**
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.		
Pharmacy has a designated non-sterile compounding supervisor (either pharmacist or pharmacy technician) Name of designated compounding supervisor:	☐	☐
Comments:		
2. Training and Skills Assessment	**S**	**U**
A skills training and assessment program is established, administered, and documented for all personnel involved in non-sterile compounding. A record is kept of assessment results and any corrective action taken. Non-compliance and corrective actions are documented. *Training and assessment elements should encompass Table 1 or similar from NAPRA Non- sterile Guidance Document*	☐	☐

Cleaning personnel are properly trained so they are aware of the importance of cleaning activities required to prevent cross-contamination. (This includes training of cleaners from third-party cleaning companies.)	☐	☐
Comments:		

3. Policies and Procedures	**S**	**U**
Documented policies and procedures for all activities related to non-sterile compounding are established, readily accessible and all staff are trained and aware of where to access them. *As per Table 3 of the NAPRA Non-sterile Guidance Document*.	☐	☐
Procedures for recall of products include documentation to ensure traceability of all ingredients included in non-sterile compounded preparations.	☐	☐
Equipment is cleaned well after each use, and regularly as recommended by the manufacturer, to disinfect and prevent cross-contamination. Cleaning log is developed to record each cleaning session. *Cleaning = Washed with soap and water, rinsed (with distilled/purified water), dried, and immediately stored away*	☐	☐
Cleaning logs are in place for daily and monthly cleanings of the work surfaces and complete room.	☐	☐
Hand hygiene policy and procedure includes all staff involved in compounding must maintain trimmed, clean nails (no nail polish or artificial nails) and jewelry on the wrists and fingers is removed and gloves are worn when compounding is performed.	☐	☐
Policy in place outlining personnel conduct within compounding area/room that includes not consuming food or drinks or chewing gum in the compounding area/room.	☐	☐
Comments:		

4. Facilities and Equipment	S	U
Facilities		
Compounding is performed in a separate, specifically designated space. Space is adequately lit, and large enough for compounding personnel to work comfortably and safely. *Level A = low traffic, designated area within the dispensary Level B = See Level B section*	☐	☐
Equipment and products are stored in an orderly, clean, and secure manner. Components, equipment, and containers are stored off the floor, allowing for appropriate cleaning and preventing contamination.	☐	☐
Work surfaces and furniture, as well as floor and wall surfaces, are designed to facilitate repeated cleaning. The countertop of designated compounding work area is non-porous, and flooring is not carpeted. Surfaces and furnishings are maintained in sanitary conditions and good repair.	☐	☐
Sink with clean water supply, with hot and cold running water, is available in compounding room (Level B) or within reasonable vicinity to compounding area (Level A).	☐	☐
Comments:		
Equipment		
Pharmacy has a clean lab coat, that is reserved for compounding, or utilizes disposable gowns. Gloves, masks, goggles and other personal protective equipment that may be required (N95 masks/respirator) available. *If utilizing a designated lab coat, must maintain a wash log verifying regular washing*	☐	☐
Working heat source available (for medication/compounding purposes only, not to be used for food or drink) *SCPP Regulatory Bylaw Requirement*	☐	☐
Class A or electronic scale	☐	☐

SCPP Regulatory Bylaw Requirement	☐	☐
Graduates (2), mortar and pestle, metal spatula, non-metal spatula, stirring rod, funnel, ointment slab and pad. *SCPP Regulatory Bylaw Requirement*	☐	☐
Equipment that is necessary for the type of preparations that are compounded is readily available. Equipment does not negatively affect the purity or quality of the preparation. *(In addition to equipment as required by SCPP Regulatory Bylaws)*	☐	☐
Comments:		
5. Product and Preparation Requirements	**S**	**U**
Master formulation records are developed/have been sourced for basic non-sterile compounds that pharmacy anticipates needing to be prepared to compound. They are readily accessible to compounding personnel and include all necessary compounding information with rationale and supporting references and have been developed based on reliable data (manufacturer's documentation, stability literature, compatibility, and ingredient degradation). This includes the determined beyond-use dates (BUDs).	☐	☐
Pharmacy is able to readily recall information (lot and expiry dates) for all ingredients of all compounds made for individual prescriptions. (Compounding record attached to patient profiles) Compounding records are kept for all non-patient specific batches prepared (anticipatory compounding), with pharmacy specific lot numbers assigned that is referred to for tracking on patient profiles when prescriptions are filled.	☐	☐
Ingredients used are obtained from recognizable and reliable sources and must be pure and of good quality (traceable). Storage conditions preserve the quality and purity of ingredients. Safety data sheets are readily accessible for all ingredients.	☐	☐
Purified water or water of equivalent or superior quality (distilled water) is used whenever the formula specifies water as an ingredient. Stored separate from ALL other diluents.	☐	☐

Comments:		
6. Quality Assurance	**S**	**U**
A Quality Assurance Program is developed and implemented ensuring the clear definition, application, and verification of all activities affecting the quality of the final product and the protection of personnel. In addition to personnel training and assessment and documented policies and procedures, the quality assurance program Includes: - Certification, maintenance, and calibration logs of equipment - Recording of temperature readings (refrigerators, freezers and when necessary, rooms.) - Incident and accident reporting involving non-sterile compounded preparations (Incident reporting into CPhIR)	☐	☐
Comments:		

Level B Non-Sterile Compounding (if applicable)

(Complex compounds, as defined in USP General Chapter 795)

Requirements in addition to Level A requirements:

Level B Requirements	**S**	**U**
Facilities		
Separate, well-ventilated room or room has a ventilated containment device (powder hood) if room is not ventilated into HVAC system. If pharmacy has powder hood, it has been certified.	☐	☐
Room must be large enough to accommodate storage of all appropriate equipment and provide an environment conducive to working comfortably with limited interruptions.	☐	☐

Room has designated sink	☐	☐

ADDITIONAL COMMENTS AND RECOMMENDATIONS FOR CLARIFICATION AND ACTION:

All deficiencies must be addressed by:

I _____, the undersigned manager of
(please print)

this pharmacy has been present during the course of this inspection and understand the observations recorded herein.

I agree to correct any deficiencies, and where necessary, provide verification of such action.

_____ _____

Signature of Pharmacy Manager Date