Alberta College of Pharmacy

This self-assessment is based on and references requirements outlined in the Alberta College of Pharmacy's (ACP) Standards for Pharmacy Compounding of Non-sterile Preparations (SPCNP) and Guidance Document for Pharmacy Compounding of Non-sterile Preparations (GPCNP). Please refer to these documents for complete lists of requirements and guidelines. **To fill out and save this document, it must be downloaded and opened with Adobe Reader.**

Level of risk	Response
Does your pharmacy provide Level A compounding?	Select
Does your pharmacy provide Level B compounding?	Select
Does your pharmacy provide Level C compounding?	Select

Risk assessment	Response
A risk assessment for each compounded product has been performed (see GPCNP Section Four).	Select
In all risk assessments, the appropriate level of requirements needed to guarantee a high-quality product and adequate protection for personnel has been identified.	Select
The cumulative risk associated with all preparations compounded in the pharmacy has been assessed.	Select
There is documentation available to all personnel specifying the potential risks of compounding the product and the extra steps that must be taken to mitigate the risk.	Select
If a small quantity of a hazardous product is used in compounding in a room outside Level C , there is documentation of alternative containment strategies and/or work practices employed to minimize occupational exposure.	Select
Safety data sheets (SDS) and other applicable references are consulted for each compound being prepared.	Select
Appropriate procedures for safe compounding are documented on the Master Formulation Record (MFR) for each compound.	Select
Additional laws and regulations governing the compounding of hazardous preparations and the handling of hazardous products are consulted for each compound.	Select
The risk assessment is reviewed at least every 12 months to ensure that it is still valid.	Select
If several different high-risk or low-risk preparations are being compounded, the cumulative risk is considered, even if they are compounded on different days.	Select
Consideration of cumulative risk is documented in the risk assessment.	Select
SDS are current and available to all employees.	Select

Level A	Response
Level A preparations are compounded in a designated, non-sterile compounding area that is large enough for compounding personnel to work comfortably and safely, with room to store equipment and products in an orderly manner, and is located in clean and secure surroundings. The area is designed and arranged to prevent cross-contamination between products, and is located away from parts of the pharmacy where there is a considerable amount of traffic (e.g., aisles, entrance, or exit).	Select
Compounding personnel underwent a skills assessment at the time of hiring.	Select

Compounding personnel have received orientation and training-during education and on the job-concerning the preparations to be compounded. The training has included learning and assimilating workplace operating procedures.	Select
Compounding personnel participate in an annual skills assessment program.	Select
Compounding personnel meet all personal protective equipment (PPE) requirements indicated in the SDS, if applicable.	Select

Level B	**Response**
Level B preparations are compounded in a ventilated, entirely closed off room or a room with a ventilated containment device.	Select
Level B preparations are compounded in an environment conducive to few or no interruptions.	Select
Level B preparations are compounded in a ventilated containment device when certain powders, aromatic products, or hazardous products are compounded.	Select
Level B preparations are compounded in an environment that meets all secondary engineering requirements as indicated in the SDS.	Select
Compounding personnel have consulted active pharmaceutical indgredient's (API) SDS and meet all PPE requirements.	Select
If a small quantity of a hazardous product is used in compounding, there must be: • a documented risk assessment that considers all cumulative risks, • documentation of alternative containment strategies, and/or • work practices being employed for specific dosage forms to minimize occupational exposure.	Select

Level C	**Response**
Level C preparations are compounded in a separate, negative pressure room.	Select
Level C preparations are compounded in an appropriate containment device.	Select
Hazardous drugs classified as Group One by the National Institute for Occupational Safety and Health (NIOSH) are considered Level C.	Select
NIOSH Group Two and Three drugs, for which large quantities of APIs are used routinely, are considered Level C.	Select
Hazardous materials classified by the Workplace Hazardous Materials Information System (WHMIS) as representing a health hazard, such as those that are very irritating to the respiratory tract, the skin or the mucous membranes, and used routinely in large quantities are considered Level C.	Select

Compounding personnel	**Response**
A non-sterile compounding supervisor has been assigned.	Select
The non-sterile compounding supervisor ensures that there are measures in place (e.g., personnel training and assessment program), to guarantee that personnel are competent to perform compounding. These measures include training for any specific populations (e.g., pediatric, geriatric, or veterinary).	Select
The non-sterile compounding supervisor ensures that the personnel know and fully comply with policies and procedures.	Select
The non-sterile compounding supervisor ensures that the existing compounding process yields high-quality non-sterile preparations.	Select
The non-sterile compounding supervisor ensures that a risk assessment is performed to determine appropriate requirements for each compounded preparation.	Select

The non-sterile compounding supervisor ensures that appropriate measures are taken to ensure the safety of personnel during each preparation.	Select
The non-sterile compounding supervisor ensures that there are procedures in place for incident/ accident reporting and follow-up, as well as recall procedures.	Select
The non-sterile compounding supervisor ensures that policies and procedures covering all activities, are developed, regularly reviewed, and updated.	Select
The non-sterile compounding supervisor ensures that the facilities and equipment used to compound non-sterile preparations meet requirements, and are maintained, calibrated, and certified, according to manufacturers' specifications or Standards for Pharmacy Compounding of Non-sterile Preparations, whichever are more stringent.	Select
The non-sterile compounding supervisor ensures that available, recognized scientific literature is used when determining the Beyond-Use Dates (BUD) for each non-sterile preparation.	Select
The non-sterile compounding supervisor ensures that MFR are developed, reviewed regularly, and updated.	Select
The non-sterile compounding supervisor ensures that an ongoing quality assurance program, designed to ensure that preparation activities are performed in accordance with standards of practice, scientific standards, existing data, and relevant information, is implemented, followed, evaluated, and updated as required.	Select
The non-sterile compounding supervisor ensures that current editions of mandatory and supplementary references - which are in compliance with provincial requirements - are available.	Select
The non-sterile compounding supervisor ensures that Safety Data Sheets are available and updated regularly, or that they are readily accessible in an electronic format.	Select
The non-sterile compounding supervisor ensures that all records of decisions, activities, or specifications required by the Standards for Pharmacy Compounding of Non-sterile Preparations are completed. Also, any changes are documented and traceable.	Select
The non-sterile compounding supervisor ensures that all records of decisions, activities, or specifications are retained and readily available for inspection purposes.	Select
Non-regulated pharmacy personnel are supervised by a pharmacist or pharmacy technician, according to established supervision protocols and appropriate quality measures.	Select

Conduct of compounding personnel in compounding areas	**Response**
Compounding personnel behave in a professional manner and follow all pertinent policies and procedures.	Select
Compounding personnel follow the procedures on the MFR.	Select
Compounding personnel perform appropriate hand hygiene before and after compounding.	Select
Compounding personnel don powder free gloves after proper hand hygiene.	Select
Compounding personnel ensure that either a clean lab coat is reserved for compounding or a disposable gown is worn.	Select
Compounding personnel ensure that if a clean laboratory coat is worn, it is reserved for making non-sterile preparations and it is not worn outside the compounding area.	Select
Compounding personnel ensure that, when the employees return to the compounding area, used laboratory coats are put on again, only when the coats are clean and unsoiled.	Select
Compounding personnel ensure that laboratory coats are changed as soon as they become soiled or according to established protocols.	Select
Compounding personnel ensure that disposable gowns are changed every day, or as soon as they become soiled.	Select

Compounding personnel ensure that other sources that might contaminate the preparation are avoided, such as • loose hair, • long or false nails, • jewellery on hands and wrists, • chewing gum, • consuming food or drink, or • using tobacco in the compounding area.	Select
Compounding personnel ensure that the compounding supervisor is notified if a compounder has an active respiratory tract infection, an eye or skin infection, a hand lesion, or other ailment.	Select
Compounding personnel ensure that, if indicated on the MFR, a cap and mask, eye protection, and a beard guard are worn.	Select
Compounding personnel ensure that any other reasonable measures are taken to prevent cross-contamination and to ensure protection from chemical exposure.	Select
Compounding personnel ensure that no food or drink is stored or consumed in the compounding area.	Select

Training and skills assessment	Response
All personnel involved in compounding possess expertise commensurate with their responsibilities.	Select
Before compounding personnel undertake non-sterile compounding, they have received the proper orientation, training, and a skills assessment concerning their work and the type of compounding to be done.	Select
A skills assessment program, which considers the type and complexity of operations performed, is established for all personnel involved in non-sterile compounding.	Select
Compliance with operating procedures and application of non-sterile compounding techniques are evaluated regularly.	Select
The skills assessment program for compounding personnel includes compliance with operating procedures and application of non-sterile compounding techniques.	Select
Cleaning personnel know all policies and procedures related to cleaning and decontaminating the equipment.	Select
Cleaning personnel know all policies and procedures related to hygiene.	Select
Cleaning personnel know all policies and procedures related to PPE.	Select
Cleaning personnel know all policies and procedures related to cleaning, decontaminating, and disinfecting tasks.	Select
Cleaning personnel know and use PPE specifically for handling hazardous products.	Select
Cleaning personnel know and use the emergency measures to be applied in case of accidental exposure, accidents, or spills.	Select

Policies and procedures	Response
Established policies and procedures provide detailed descriptions of all activities, including cleaning of everything related to the pharmacy's compounding of non-sterile preparations.	Select
The non-sterile supervisor ensures application of and compliance with the policies and procedures.	Select
Established policies and procedures are promptly updated whenever there is a change in practice or standards.	Select
Policies and procedures are reviewed every 12 months at a minimum to ensure that they are current.	Select

Additional policies and procedures for handling or compounding hazardous drugs or materials have been developed, including the safe receipt, storage, handling, compounding, labelling, transport, and disposal of hazardous drugs and materials.	Select
When compounding is undertaken by another pharmacy, the dispensing facility has included in its general procedures' manual, information about policies and procedures for acquiring compounded non-sterile preparations for patients (e.g., originating pharmacy, entry in the file, delivery, etc.).	Select

Facilities and equipment	Response
If a pharmacy or healthcare facility compounds any sterile preparations, the area of the pharmacy reserved for this purpose is separate and distinct from the area of the pharmacy set aside for non-sterile compounding.	Select
All compounding is performed in a separate space specifically designated for compounding of prescriptions.	Select
The compounding space is located away from parts of the pharmacy where there is a considerable amount of traffic (e.g., aisles, entrances, or exits, etc.)	Select
Compounding areas are large enough for compounding personnel to work comfortably and safely, with room to store equipment and products in an orderly manner, in clean and secure surroundings.	Select
All components, equipment, and containers are stored off the floor, in a manner that prevents contamination and allows for inspection and cleaning of the compounding and storage area.	Select
The compounding area is conducive to necessary cleaning and it does not contain any areas that are difficult to clean.	Select
The area used for non-sterile compounding is maintained in clean, orderly, and sanitary conditions, with appropriate and sanitary waste disposal, and it is maintained in a good state of repair.	Select
The lighting fixtures are located in a way that it provides a well-lit area which facilitates the compounding process and allows verification at all stages of compounding.	Select
The heating, ventilation, and air conditioning system is controlled in such a way as to avoid decomposition and contamination of chemicals, to maintain the quality and efficacy of stored products and to ensure the safety and comfort of compounding personnel.	Select
Air vents are not located directly over work areas to avoid contamination of the products.	Select
Compounding areas must contain an eyewash station and other emergency or safety equipment that is required. Licensees should determine the type of eyewash station that is appropriate based on their non-sterile compounding risk assessment.	Select
For Level A compounding requirements, a clean water supply with hot and cold running water is available in or close to the compounding area.	Select
For Level B and Level C requirements, a clean water supply, with hot and cold running water, is available in the compounding room, at least one meter away from the containment primary engineering control (C-PEC).	Select
Work surfaces and furniture are constructed of smooth, impervious, and non-porous materials, preferably stainless steel.	Select
Any breakage is repaired and sealed at the earliest opportunity.	Select
All furniture, as well as the floor and wall surfaces, have been designed and placed to facilitate cleaning and disinfecting.	Select
A cleaning schedule appropriate to the level and type of non-sterile compounding has been established.	Select
The worktop surface used for non-sterile compounding is cleaned before and after each compounding session.	Select
The equipment, instruments, and accessories chosen are appropriate for the type of preparations to be compounded, and are reserved for compounding activities.	Select

Any surfaces of instruments and accessories that come into contact with preparations do not negatively affect the purity or quality of the preparation being compounded.	Select
To ensure precision and reliability, all equipment, instruments, and accessories are routinely inspected and checked to ensure proper performance. Also, if applicable, they are calibrated at appropriate intervals as recommended by the manufacturer, or at least once a year if there are no manufacturer recommendations.	Select
All specialized equipment and instruments used for compounding are cleaned regularly, as recommended by the manufacturer.	Select
Cleaning work recommended by the manufacturer is noted in the maintenance log.	Select
Equipment, instruments, and accessories used for several different preparations are completely and thoroughly cleaned after each compounding session to remove all traces of the previous product, and any remaining water and solvent. This prevents any cross-contamination between preparations.	Select
A maintenance log is kept to record the dates of cleaning and/or calibration of specialized equipment and instruments. These entries include the name of the person carrying out the cleaning or calibration.	Select

Beyond-Use Date (BUD)	**Reponse**
The BUD is determined by regulated pharmacy personnel with adequate experience and broad scientific knowledge.	Select
The BUD is assigned after consulting the manufacturer's documentation and literature on the stability, compatibility, and degradation of ingredients.	Select
The manufacturer's expiry date for the drug is not used as the BUD for the final preparation.	Select
For non-aqueous formulations, in the absence of any stability data for a drug or a specific non-sterile compounded preparation, the BUD is not later than the time remaining until the earliest expiry date of any API or 6 months, whichever is earlier (GPCNP 6.1.1).	Select
For water-containing oral formulations, in the absence of any stability data for a drug or a specific non-sterile compounded preparation, the BUD is not later than 14 days with storage at controlled cold temperatures (GPCNP 6.1.1).	Select
For water-containing topical/dermal, mucosal liquid and semi-solid formulations (such as preparations for topical application, like creams, gels, etc.), in the absence of any stability data for a drug or a specific non-sterile compounded preparation, the BUD is not later than 30 days (GPCNP 6.1.1).	Select

Master Formulation Record (MFR)	**Response**
The MFR has been developed for each non-sterile compound by regulated pharmacy personnel with adequate experience and broad scientific knowledge.	Select
The MFR includes all necessary information to compound the non-sterile preparation.	Select
The MFR contains supporting rationale and references.	Select
The MFR is kept in a format that is readily accessible to compounding personnel.	Select

Quality and storage of ingredients	**Reponse**
The ingredients used for compounding are pure and of good quality.	Select
Purified water or water of equivalent or superior quality is used whenever the formula specifies water as an ingredient.	Select
Tap water is not used for compounding products.	Select
The ingredients used for compounding are obtained from recognized and reliable sources.	Select
The sources of ingredients used for compounding, as well as lot numbers, expiry dates, and date of receipt in the pharmacy must be traceable.	Select

Ingredients for compounding that have been recalled or withdrawn from the market for safety reasons are not used.	Select
Current SDS are readily accessible for all ingredients.	Select
Ingredients used for compounding are stored under conditions that will preserve their purity and quality.	Select
For ingredients without an expiry date assigned by the manufacturer, the container is labelled with the date of receipt and a conservative expiry date. This expiry date, depending on the nature of the ingredient, the container, and storage conditions, does not exceed three years after receipt of the ingredients.	Select

Compounding record	**Reponse**
The compounding record is kept for each individual prescription and for non-sterile preparations made in batches. It can be paper-based or an electronic form.	Select
In cases where the preparation was made by another pharmacy, the origin of the compounded non-sterile preparation dispensed to the patient is recorded in the patient's file.	Select

Verification of final compounded non-sterile preparations	**Reponse**
Verification is performed at each stage of the compounding process.	Select
Final verification takes place before the preparation is dispensed.	Select
The MFR and compounding record are reviewed to ensure no errors have occurred in the compounding process and the preparation is suitable for use.	Select
All information on the final label is verified, including the BUD.	Select

Labelling and packaging	**Reponse**
A policy for labelling and packaging has been established and is followed.	Select
The label and supplemental label provide all the information required for proper use of the compounded preparation, by the patient or for safe administration by a third party.	Select
Special precautions related to drug storage (e.g., refrigeration) are included on the label or supplemental label.	Select
All active ingredients and the concentration of the active ingredients are identified on the label.	Select
The label includes the BUD, storage, and handling information.	Select
Packaging used is appropriate to maintain the integrity of the compounded preparation.	Select

Storage	**Reponse**
A storage procedure has been established and is followed.	Select
Active and inactive ingredients are stored according to manufacturer's recommendations, in a manner that prevents cross-contamination.	Select
Each finished product is stored according to requirements outlined in the MFR.	Select
Products that have been stored are inspected before use to detect any signs of deterioration.	Select

Transport and delivery	**Reponse**
Policies for transport and delivery have been established.	Select
Policies for transport and delivery address special precautions for non-sterile compounded products.	Select
Preparations for delivery are packed and labelled in a manner that ensures the safety of patients and delivery persons.	Select
Transport conditions related to temperature, fragility, and safety are indicated on the outside of the packaging.	Select

Product recalls	Reponse
Procedure for recall of products includes documentation that ensure traceability of all ingredients included in the non-sterile products.	Select

Incident reporting	Reponse
An incident report is completed for any incident or accident involving a compounded non-sterile product.	Select
Complaints, accidents, incidents, and reported side effects are evaluated to determine the cause. Necessary steps are taken to prevent a recurrence.	Select

Quality assurance	Reponse
A quality assurance program has been 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.	Select
Equipment used for compounding is certified at regular intervals and at installation.	Select
Temperature readings are taken at regular intervals to ensure the integrity of products stored in refrigerators, in freezers, or at room temperature.	Select
Compounding personnel are trained, certified, and reassessed at regular intervals to ensure maintenance of competency.	Select
Non-compliance with the quality assurance program and corrective actions are documented.	Select

Hazardous preparations	Reponse
The risk assessment for hazardous materials is reviewed at least every 12 months.	Select
Facilities for handling hazardous products have been constructed to minimize the risk of exposure to compounding personnel and other pharmacy staff.	Select
For Level C compounding requirements, the compounding room is ventilated through high-efficiency particulate air (HEPA) filtration. It has appropriate air exchange and it has negative pressure relative to surrounding rooms.	Select
The compounding room has been constructed with smooth impermeable surfaces to promote adequate cleaning and decontamination.	Select
The heating, ventilation, and air conditioning system in the compounding room has been constructed to prevent contamination of the areas surrounding it and to ensure the comfort of personnel wearing PPE.	Select
Windows and other openings in the compounding room do not lead directly outside or to a non-controlled area.	Select
There is an appropriate area for unpacking hazardous products, and a C-PEC is available for unpacking hazardous products that appear to be damaged.	Select
Hazardous products are stored in a room with appropriate ventilation.	Select
Areas for storing and preparing hazardous products are identified with appropriate signage.	Select
A C-PEC that provides appropriate personal and environmental protection has been installed and maintained.	Select
All reusable equipment and devices are adequately deactivated, decontaminated, and cleaned.	Select
For hazardous compounding, dedicated compounding equipment and dedicated cleaning equipement are used.	Select

PPE approved for the compounding of hazardous non-sterile preparations are worn during compounding activities, including • chemotherapy gloves, • disposable, impermeable gown, • head, hair, shoe and sleeve covers, • respiratory protection, and • eye and face protection.	Select
Compounding area, equipment, and accessories are meticulously cleaned.	Select
Cleaning is done to eliminate chemical contamination, specifically by deactivating, decontaminating, and cleaning the premises and equipment.	Select
Cleaning personnel comply with the pharmacy's hand hygiene and garbing procedure for handling hazardous products.	Select
The work surface of the C-PEC is deactivated, decontaminated, and cleaned before starting the compounding of a different preparation.	Select
Policies and procedures have been developed and followed for cases of accidental exposure of personnel to hazardous products.	Select
Personnel receive training to prevent spills, as well as training on appropriate procedures to clean up spills, including use of a spill kit.	Select
Incidents and accidents are documented and followed up to prevent recurrence.	Select
Procedures are in place for the destruction and/or disposal of pharmaceutical waste in compliance with environmental protection legislation.	Select
All personnel involved in the management of hazardous product waste receive appropriate training and have access to all necessary PPE and cleaning supplies.	Select
The controlled room and C-PEC are examined and certified every 6 months, according to manufacturer's recommendations, as appropriate. This will happen more often in the case of new equipment installation, repairs, or a contamination problem.	Select
Manufacturers' factory-issued certificates for all HEPA filters and C-PECs are retained for the service life of the equipment.	Select
An environmental verification program has been established to ensure safety standards.	Select
All completed documentation concerning components of testing of controlled rooms and equipment for hazardous product contamination are filed and retained with other compounding records.	Select