Newfoundland & Labrador Pharmacy Board

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Pharmacy Quality Assurance Self-Assessment

(Non -Sterile Compounding –Non-Hazardous and Hazardous)

Contact Information	
Pharmacy:	**License #:**
Address:	**PO Box:**
City/Town:	**Postal Code:**
Phone #:	**Fax #:**
Email Address:	**Website:**

Hours of Operation			
Mon-Fri:	**Sat:**	**Sun:**	**Holidays:**

Level of Compounding Provided		
❑ **Level A**	❑ **Level B**	❑ **Level C**

Pharmacy Staff		
Position:	**Name:**	**License Number (if applicable):**
Pharmacist-in-Charge		
Compounding Supervisor		
Additional Compounding Personnel:		

Advancing Pharmacy Care for a Safe and Healthy Community

COMPLIANCE CHECKLIST

Please indicate compliance by checking the appropriate space below. If the pharmacy is not in compliance, please

	Compliant			Comments
	Yes	No	N/A	
GENERAL				
Pharmacy peronnel are aware of the definition of compounding and how to differentiate between compounding and manufacturing				
Consideration is given upfront to whether or not the pharmacy should compound a given preparation (ensuring appropriate ingredients, space, equipment, personnel training, referenced formulation, stability data)				

RISK ASSESSMENT *(Standard 4)*				
A decision algorithm and appropriate references are used to carry out risk assessments (see *Guidance Document - Section 4.2, 4.3*)				
For each compound, safety data sheets and other applicable references are consulted, including any additional provincial laws and regulations that govern compounding and handling of hazardous products, and workplace safety				
WHIMIS safety data sheets are available to all employees				
For each compounded product, a risk assessment has been conducted to identify the appropriate level of requirements to minimize risk to the preparation and risk to persons				
The preparation area is free from interuptions, is large enough for compounding equipment and ingredients, and consideration is given to ensure that nothing in the surrounding area contaminates the compounded preparation				
Compounding personnel are protected from materials that may be hazardous or harmful, and the environment is contained in a way that it does not create a hazardous environment for others				
For each compound, the rationale for the risk assessment and appropriate procedures for safe compounding/risk mitigation are documented on the Master Formulation Record				
Consideration of cumulative risk is documented in risk assessments				
A process is in place to review each risk assessment at least **every 12 months** to ensure that it is still valid				
The cumulative risk associated with **all** preparations compounded in the pharmacy is regularly assessed. For example, 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				
The level of facility requirements in place is based on the risk associated with compounding activities (Level A, B, C)				
When there is any uncertainty about risk level, the pharmacy applies the requirements for the higher risk level				

	Compliant			Comments
	Yes	No	N/A	
COMPOUNDING PERSONNEL *(Standard 5.1, Standard 6)*				
A non-sterile compounding supervisor is in place and is responsible for ensuring:				
development, organization and oversight of all activities related to non-sterile compounding				
implementation of personnel training processes and competency assessments, and orientation to policies and procedures				
completion of risk assessments for all compounds at the required frequency				
facility and equipment requirements are met for the level of compounding services provided by the pharmacy				
appropriate references are available to compounding personnel				
required policies and procedures are developed, regularly reviewed and updated				
master formula and beyond-use-dating are developed based on appropriate references and are regularly reviewed				
a quality assurance program is implemented, followed, evaluated and updated as required				
required documentation processes are in place and records are retained in a readily retrievable manner				
appropriate supervision of non-regulated pharmacy personnel				
The **conduct** of compounding personnel is aligned with the standards (*Standard 6 and Guidance Document Section 6.5*) including that:				
Professional behavior and adherence to all pertinent policies and procedures is demonstrated				
Appropriate hand hygiene is performed, before and after compounding				
Powder free gloves are donned after proper hand hygiene				
A clean lab coat reserved for compounding or a disposable gown is worn				
Sources that might contaminate preparations are not permitted in the compounding area (loose hair, long or false nails, jewelry on hands or wrists, chewing gum, food/drink)				
The compounding supervisor is notified if the compounder has an active respiratory tract infection, an eye or skin infection, a hand lesion or other ailment, and the personnel limits their participation in compounding when required				
Personal protective equipment or other equipment identified on the Master Formulation Record is worn during product prepartion (e.g. cap, mask, eye protection, beard guard, additional or specfic gloves, specfic gown, etc.)				
Any other reasonable measures are taken to prevent cross-contamination and to ensure protection from chemical exposure.				
Decisions, completed activities and verifications are clearly documented in a readily retrievable manner				

	Compliant			Comments
	Yes	No	N/A	
TRAINING AND SKILLS ASSESSMENT *(Standard 5.2)*				
All personnel involved in compounding possess expertise commensurate with their responsibilities. To ensure this:				
A training program is in place for all compounding personal and a record of all training is kept in a readily retrievable manner				
A skills assessment program is established, administered, and documented for all compounding personnel and a record is retained of individual assessment results and any corrective actions taken				
The recommended components for training and skills assessment outlined in the related section of the *Guidance Document* are integrated into established processes				
Compliance with operating procedures and application of non-sterile compounding techniques are evaluated regularly under the skills assessment program				
Cleaning personnel are properly trained, understand and follow all policies and procedures related to:				
cleaning and decontaminating the equipment				
cleaning and decontaminating furniture and facilities				
hygiene				
personal protective equipment				
cleaning and disinfecting tasks				
emergency measures to be applied in case of accidental exposure, accidents or spills.				

POLICIES AND PROCEDURES *(Standard 5.3)*				
Policies and procedures are in place for all activities related to non-sterile compounding (including cleaning) and a regular review cycle has been established (see section 5.3.1 of the guidance document for a list of recommended policies and procedures)				
Policies are procedures are clear and detailed				
A review process is established so that policies and procedures are reviewed and updated at least every 3 years				
Additional policies and procedures are in place for handling or compounding hazardous drugs or materials, including the safe receipt, storage, handling, compounding, labelling, transport and disposal				

	Compliant			Comments
	Yes	No	N/A	
FACILITIES AND EQUIPMENT *(Standard 5.4, Standard 8)* *Required for **ALL** levels of compounding; additional requriements are outlined for Level B and C*				
Compounding is performed in a separate space specifically designated for compounding of prescriptions which is:				
located away from parts of the pharmacy where there is a considerable amount of traffic (aisles, entrance and exit doors, etc.) (IF THE PHARMACY LAYOUT DOES NOT PERMIT, STATE RISK MITIGATION MEASURES IN COMMENTS)				
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				
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				
The compounding area is conducive to necessary cleaning, is maintained in sanitary condition and is in good repair				
Work surfaces are constructed of smooth, impervious, non-porous materials (preferably stainless steel)				
All furniture, as well as the floor and wall surfaces, have been designed and placed to facilitate cleaning and disinfecting				
A cleaning schedule appropriate to the level and type of non-sterile compounding has been established				
The worktop surface used for non-sterile compounding is cleaned before and after each compounding session				
Appropriate systems are in place for waste disposal				
The lighting fixtures provide sufficient light for compounding activities and preparation verification				
The heating, ventilation and air conditioning system is controlled and prevents decomposition and contamination of chemicals, maintains the quality and efficacy of stored products, and ensures the safety and comfort of compounding personnel, including that:				
humidity and temperature monitoring is in place				
air vents are not located directly over work areas				
A clean water supply, with hot and cold running water, is available in (level B, C) or close to (level A) the compounding area				

	Compliant			Comments
	Yes	No	N/A	
FACILITIES AND EQUIPMENT *(Continued)*				
The equipment, instruments and accessories used for compounding are:				
appropriate for the type of preparations to be compounded, and are reserved for compounding activities				
do not negatively affect the purity or quality of preparations				
routinely inspected and checked to ensure proper performance and, if applicable, calibrated at appropriate intervals as recommended by the manufacturer, or at least once a year if there are no manufacture recommendations				
cleaned regularly, as recommended by the manufacturer				
are completely and thoroughly cleaned after each compounding session to remove all traces of the previous product and any remaining water and solvent, thus preventing any cross-contamination between preparations				
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.				

LEVEL A REQUIREMENTS *The level of requirements that must be met when compounding simple or moderate compounds, as defined in USP 795*				
A designated compounding area is defined (does not have to be a separate room, but must meet general requirements)				

LEVEL B REQUIREMENTS *The level of requirements that must be met when compounding complex preparations, as defined in USP 795, or when compounding small quantities of products that require ventilation; these preparations generally require more specialized equipment, instruments, and personnel training*				
The pharmacy has a separate, well-ventilated room that is conducive to few or no interuptions and provides greater protection from cross contamination				
The compounding room has a sanitary sink				
The facility has appropriate equipment and workspace to support more complex compounding activites				
The pharmacy has a ventilated containment device that is used when certain powders, aromatic products or hazardous products are compounded				

	Compliant			Comments
	Yes	No	N/A	
LEVEL C REQUIREMENTS *The level of requirements that must be met when compounding any amount and any dosage form of hazardous drugs that are classified by NIOSH as Group 1, or when compounding using materials that are classified as a health hazard by WHIMIS (e.g. respiratory tract, skin or mucous membrane irritants), or when compounding NIOSH group 2 or 3 drugs involving routine use of a large quantity of APIs*				
The pharmacy has a separate, well-ventilated negative pressure room with appropriate air exchange that is used exclusively for level C compounding (If a level C room is utilized for non-hazardous non-sterile compounding, the pharmacy must be able to ensure that risks of cross-contamination have been mitigated (e.g. dedicated equipment, decontamination processes). If this is the case, INDICATE RISK MITIGATION MEASURES IN THE COMMENTS)				
The compounding room has a sink				
The pharmacy has an appropriate containment device for compounding level C compounds (i.e. Containment Primary Engineering Control [CPEC])				
The pharmacy handles hazardous drugs classified as Group 1 by NIOSH as Level C				
The pharmacy handles hazardous materials classified by WHMIS as representing a health hazard, such as those that are very irritating to the respiratory tract, the skin or the mucous membranes as Level C				
The pharmacy handles NIOSH Group 2 and 3 drugs for which large quantities of APIs are used as Level C				

PRODUCT AND PREPARATION REQUIREMENTS *(Standard 6)*				
Beyond-use dating (BUD) *(Guidance Document - Section 6.1)*				
BUD is determined by regulated pharmacy personnel with adequate experience and broad scientific knowledge				
BUD is assigned after consulting the manufacturer's documentation and literature on the stability, compatibility and degradation of ingredients				
Compounded products are monitored for signs of instability and/or degradation				
In the absence of stability data, BUD assignment does not exceed the recommendations in Table 4 of the guidance document				
Master formulation record *(Guidance Document - Section 6.2)*				
A master formulation record has been developed for each non-sterile compound by regulated pharmacy personnel with adequate experience and broad scientific knowledge				
Master formulation records include all necessary information to compound the non-sterile preparation and are based on the recommendations outlined in the guidance document section 6.2				
The master formulation record contains supporting rationale and references				
The master formulation record is kept in a format that is readily accessible to compounding personnel				

	Compliant			Comments
	Yes	No	N/A	
PRODUCT AND PREPARATION REQUIREMENTS *(Continued)*				
Ingredients used for compounding *(Guidance Document - Section 6.3)*				
The ingredients used for compounding are pure and of good quality				
Purified water or water of equivalent or superior quality is used whenever the formula specifies water as an ingredient				
The ingredients used for compounding are obtained from recognized and reliable sources				
The sources of ingredients used for compounding, as well as lot numbers, expiry dates and date of receipt, is documented in a retrievable, auditable, and traceable manner				
Ingredients for compounding that have been recalled or withdrawn from the market are not used				
Current safety data sheets are readily accessible for all ingredients.				
Ingredients used for compounding are stored under conditions that will preserve their purity and quality				
For ingredients **without** an expiry date assigned by the manufacturer, the container is labelled with the date of receipt and a conservative expiry date, that **does not exceed 3 years after receipt**, depending on the nature of the ingredient, the container and storage conditions.				
Compounding records *(Section 6.4, Guidance Document)*				
A compounding record is kept for each individual prescription and for non-sterile preparations made in batches (paper-based or electronic)				
Compounding records contain all relevant information as recommened in section 6.4 of the guidance document				
Compounding records are retained in a readily retrievable manner				
Verfication of final compounded non-sterile preparations *(Section 6.6, Guidance Document)*				
Verification is performed at each stage of the compounding process.				
Final verification takes place before the preparation is dispensed				
The master formulation record and compounding record are reviewed to ensure no errors have occurred in the compounding process and the preparation is suitable for use.				
All information on the final label is verified, including the BUD				

	Compliant			Comments
	Yes	No	N/A	
PRODUCT AND PREPARATION REQUIREMENTS *(Continued)*				
Labelling and packaging *(Section 6.7, Guidance Document)*				
A policy for labelling and packaging has been established and is followed				
The label and supplementary label provides all the information required for proper use of the compounded preparation by the patient or for safe administration by a third party				
Special precautions related to drug storage (i.e. refrigeration) are included on the label or supplemental label				
All active ingredients and the concentration of the active ingredients are identified on the label				
The label includes the BUD, storage and handling information				
Packaging used is appropriate to maintain the integrity of the compounded preparation and to protect the safety of patients and delivery personnel				
Storage *(Section 6.8, Guidance Document)*				
A storage procedure has been established and is followed				
Active and inactive ingredients are stored according to manufacturer's recommendations, in a manner that prevents cross-contamination				
Each finished product is stored according to requirements outlined in the master formulation record				
Products that have been stored are inspected before use to detect any signs of deterioration				
Transport and delivery *(Section 6.9, Guidance Document)*				
Policies for transport and delivery have been established				
Policies for transport and delivery address special precautions for non-sterile compounded products				
Transport conditions related to temperature, fragility and safety are indicated on the outside of the packaging				
Product recalls *(Section 6.10, Guidance Document)*				
The pharmacy has a recall procedure that includes the ability to indentify patients that have received a specfic compounded preparation, a notification process, and follow-up				
Procedures for recall of products include documentation that ensure traceability of all ingredients included in each non-sterile preparation				
Incident reporting *(Section 6.11, Guidance Document)*				
The pharmacy has a template for incident/accident reporting and follow-up, and all staff are familiar with where to access the form				
An incident report is completed for any incident or accident involving a compounded non-sterile product				
Complaints, accidents, incidents and reported side effects are evaluated to determine the cause, and necessary steps are taken to prevent a recurrence				

	Compliant			Comments
	Yes	No	N/A	
QUALITY ASSURANCE *(Standard 7)*				
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 (see Table 6 of the guidance document for recommended QA activities)				
Equipment used for compounding is certified at regular intervals and at installation				
Temperature readings are taken at regular intervals to ensure the integrity of products stored in refrigerators, in freezers, or at room temperature				
Compliance with policies and procedures is monitored				
Quality assurance activities are appropriately documented in a readily retrievable manner, including non-compliance with the quality assurance program and any corrective actions that are taken				

REQUIREMENTS FOR HAZARDOUS PREPARATIONS *(Standard 9)*				
The risk assessment for hazardous materials is reviewed at least every 12 months.				
Facilities for handling hazardous products have been constructed to minimize the risk of exposure to compounding personnel and other pharmacy staff				
The compounding room:				
contains an eyewash station and any other emergency or safety equipment required				
has been constructed with smooth impermeable surfaces to promote adequate cleaning and decontamination				
The heating, ventilation, and air conditioning system in the compounding room has been constructed to prevent contamination of the areas surrounding the compounding room and to ensure the comfort of personnel wearing PPE				
Windows and other openings in the compounding room do not lead directly outside or to a non-controlled area				
There is an appropriate area for unpacking hazardous products and a C-PEC is available for unpacking hazardous products that appear to be damaged				
Hazardous products are stored in a room with appropriate ventilation				
Areas for storing and preparing hazardous products are identified with appropriate signage				
A C-PEC that provides appropriate personal and environmental protection has been installed and maintained				
All reusable equipment and devices are adequately deactivated, decontaminated and cleaned				

	Compliant			Comments
	Yes	No	N/A	
REQUIREMENTS FOR HAZARDOUS PREPARATIONS *(Continued)*				
PPE approved for the compounding of hazardous non-sterile preparations are worn during compounding activities:				
chemotherapy gloves				
disposable, impermeable gown				
head, hair, shoe and sleeve covers				
respiratory protection				
eye and face protection				
Compounding area, equipment and accessories are meticulously cleaned to eliminate chemical contamination, specifically by deactivating, decontaminating and cleaning the premises and equipment				
Walls, ceiling, and storage areas are cleaned at least once per year, or more frequently if necessary				
Floors are washed at least once per day or more frequently if necessary				
Deactivation, decontamination and cleaning products are carefully selected based on surface compatibility and safety				
Safety data sheets are available for all deactivation, decontamination and cleaning products				
Only trained and qualified cleaning and disinfecting personnel are permitted to clean controlled areas				
Cleaning personnel comply with the pharmacy's policies and procedures, including hand hygiene and garbing procedure for handling hazardous products				
The work surface of the C-PEC is deactivated, decontaminated and cleaned before starting the compounding of a different preparation				
The tray under the work area of the C-PEC is cleaned at least monthly (if applicable)				
The whole C-PEC is deactivated, decontaminated and cleaned at least daily when in use, any time a spill occurs, before and after certification, and any time there is voluntary interuption or it is moved				
Deactivation, decontamination and cleaning activities are recorded in the general maintenance log				
Policies and procedures have been developed and followed for cases of accidental exposure of personnel to hazardous products				
Personnel receive training to prevent spills, as well as training on appropriate procedures to clean up spills, including use of a spill kit				
Incidents and accidents are documented and followed up to prevent recurrence				

	Compliant			Comments
	Yes	No	N/A	
REQUIREMENTS FOR HAZARDOUS PREPARATIONS *(Continued)*				
Procedures are in place for the destruction and/or disposal of pharmaceutical waste in compliance with environmental protection legislation				
All personnel involved in the management of hazardous product waste receive appropriate training and have access to all necessary PPE and cleaning supplies				
The controlled room and C-PEC are examined and certified **every 6 months** according to manufacturer's recommendations, as appropriate (and more often in the case of new equipment installation, repairs or a contamination problem)				
Manufacturers' factory-issued certificates for all HEPA filters and C-PECs are 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 are filed and retained with other compounding records				

CERTIFICATION

Completed by: _____ Date: _____

I, _____, certify that:

❑ To the best of my knowledge, the information provided in this self-assessment accurately reflects the pharmacy's current operations and practices.

❑ An action plan will be put in place to fully meet the Standards for Pharmacy Compounding of Non-Sterile Preparations within a timeframe satisfactory to the NL Pharmacy Board.

❑ I will keep a copy of this completed self-assessment on file at the pharmacy and will present it to the NL Pharmacy Board upon request.

_____ _____

Pharmacist-in-Charge Signature Date Signed