Non-Sterile Preparations Assessment Criteria

Model Standards for Pharmacy Compounding of Non-Sterile Preparations

The following chart outlines key **NAPRA Model Standards for Pharmacy Compounding of Non-sterile Preparations** (the Standards), divided by sections, with each statement in the first column representing a specific standard to be met. The guidance column references the corresponding sections of the accompanying **NAPRA Guidance Document for Pharmacy Compounding of Non-sterile Preparations** (Guidance Document or GD) and illustrates specific insights or activities required to ensure adherence to the standard.

This document is provided to assist practitioners in understanding expectations, conducting a gap analysis to current processes, and preparing for full implementation of the Standards. For each standard, check the guidance that your pharmacy has in place and continue to work on achieving the remaining criteria prior to the implementation date.

Section 2: Objectives and Section 3: Regulatory Framework - Implementation Timeline Link	
STANDARD	**GUIDANCE**
The pharmacist or pharmacy technician uses professional judgment to determine if non-sterile compounding is appropriate.	☐ The pharmacist or pharmacy technician must consider the general guidance in Section 2.1 of the Guidance Document when determining whether to compound a non-sterile preparation. See **Assessing Knowledge and Technique when Compounding** and **GD – Section 2.1**.
	☐ Review the questionnaire in Section 3.1 of the Guidance Document, which provides general guidelines to differentiate between non-sterile compounding and manufacturing activities. See **GD – Section 3.1**, as well as the Policy on Manufacturing and Compounding Drug Products in Canada.
	The pharmacy must: ☐ have a process in place to ensure when dispensing compounded product to a prescriber's order for office use that a valid patient-healthcare professional relationship exists.

	☐ have a process in place to ensure the preparation of a compounded product at an appropriate scale, time, and frequency.

Section 4: Assessing Risk for Compounding Non-Sterile Products Implementation Timeline Link	
STANDARD	**GUIDANCE**
A risk assessment has been performed to identify the appropriate level of requirements to minimize contamination of **each** non-sterile compounded product and to provide adequate protection for personnel.	☐ A risk assessment must be undertaken for each non-sterile compounded product, covering risk to preparation and risk to person. Factors to consider include items listed at the bottom of page 7 of the **GD – Section 4 /4.1.**
	☐ The risk assessment must be reviewed at least every 12 months to ensure that it is current or more frequently if there is a change in practice or standards. **GD – Section 4 /4.1**
	☐ Use the Decision Algorithm for Risk Assessment in Section 4.2 of the Guidance Document to determine risk. The requirements for safe non-sterile compounding of all materials must be researched and documented. Safety data sheets and other applicable references must be consulted, and appropriate procedures for safe compounding must be documented on the Master Formulation Record. **GD – Section 4 /4.2**
	☐ Review Section 4.3 in the NAPRA Guidance Document which contains references for assessing risk. **GD – Section 4.3**

Section 5: Requirements for All Levels of Non-Sterile Compounding Activities Implementation Timeline Link	
STANDARD	**GUIDANCE**
The Pharmacy Manager is responsible for all activities related to non-sterile compounding.	☐ The Pharmacy Manager has overall responsibility for the development, organization, and supervision of all activities related to the compounding of non-sterile preparations in the pharmacy. These responsibilities may be assigned to a pharmacist or pharmacy technician who will be designated the non-sterile compounding supervisor (**GD - Section 5.1** and

	Section 20.2 of the Regulations of the New Brunswick College of Pharmacists).
	☐ The non-sterile compounding supervisor is responsible for ensuring the requirements outlined in Section 5.1.2 Guidance Document are met. **GD - Section 5.1.2**
Policies and procedures are in place for all activities related to non-sterile compounding.	☐ Policies and procedures for all activities related to non-sterile compounding must be established and be readily retrievable to compounding staff. Policies and procedures must provide detailed descriptions of all activities, including cleaning. **GD - Section 5.3**
	☐ Review Sections 5.3.1 and 5.3.2 in the Guidance Document for examples of, and template for, policies and procedures. **GD - Sections 5.3.1 & 5.3.2**
	☐ Policies and procedures must be reviewed at least every 3 years, or more frequently if there is a change in practice or standards. **GD - Section 5.3**
	☐ The pharmacy must have a process in place to verify (using an independent check where possible) each critical step (calculations, selection and measurement of ingredients, mixing technique (if applicable), as well as a check of the finished product, regardless of the individuals preparing the product). Documentation of sign off for each critical step is required. **GD - Section 5.2.1.1**
All personnel involved in non-sterile compounding have the required expertise.	☐ Non-sterile compounding personnel must know and comply with established policies and procedures. **GD – Section 5.1**
	☐ A training and skills assessment program must be established, administered, and documented for all personnel involved in non-sterile compounding. **GD – Section 5.2**
	☐ Review Table 1 in Section 5.2.1 in the Guidance Document for elements to cover in the training of non-sterile compounding personnel. Also, review Checklist 1 in **Section 5.2.1.1 in the Guidance Document** for an example of a skills assessment for the steps in the non-sterile compounding process.

	☐ Cleaning personnel (if separate from pharmacy team members) must be trained and aware of roles and responsibilities as outlined in Table 2 in **Section 5.2.2 of the Guidance Document.**
Non-sterile compounding is performed in a separate, specifically designated space that is appropriate for compounding and maintained to ensure the quality and integrity of the final preparation.	☐ All non-sterile compounding must be performed in a space specifically designated for compounding of prescriptions, which should be located away areas where there is a considerable amount of traffic. The space must be large enough for the orderly placement of equipment and products, to avoid cross-contamination, and for compounding personnel to work comfortably and safely. **GD – Section 5.4.1**
	☐ The areas used for non-sterile compounding must be in a good state of repair and maintained in clean, orderly, and sanitary conditions with appropriate and sanitary waste disposal. **GD – Section 5.4.1**
	☐ All components, equipment, and containers must be stored off the floor. To limit the accumulation of dust and particles, packaging and cardboard boxes from products used should not be allowed in the non-sterile compounding area. **GD – Section 5.4.1**
	☐ The heating, ventilation, and air conditioning system must be controlled in such a way as to avoid decomposition and contamination of chemicals, to maintain the quality of stored products, and to ensure the safety and comfort of non-sterile compounding personnel. **GD – Section 5.4.1.3**
	☐ Air vents may not be located directly over work areas, to avoid contamination of the products. **GD – Section 5.4.1.3**
	☐ Work surfaces and furniture, as well as floor and wall surfaces, must be designed and placed to facilitate cleaning (e.g. constructed of smooth, impervious, and non-porous materials that are able to withstand repeated cleaning and disinfecting). **GD – Section 5.4.1.5**
A clean water supply, with hot and cold running water, is available in or close to the non-sterile compounding area	☐ A clean water supply, with hot and cold running water, must be available in or close to the non-sterile compounding area

	or, for Level B and Level C requirements, in the non-sterile compounding room. **GD – Section 5.4.1.4**

Section 6: Product and Preparation Requirements Implementation Timeline Link	
STANDARD	**GUIDANCE**
Beyond-use dates (BUDs) are to be assigned to each non-sterile compound prepared in the pharmacy.	☐ Beyond-use dates (BUDs) are to be assigned conservatively ("when in doubt, defer to the higher standard"). **GD – Section 6.1**
	☐ When assigning BUDs, literature and documentation available on stability in general and on the specific stability of the active pharmaceutical ingredient (API) must be consulted. **GD – Section 6.1**
	☐ When determining beyond-use dates, other considerations to include are the nature of the ingredient to be used, the compounding method, degradation mechanisms, compatibility, dosage form, potential for microbial proliferation in the preparation, the container in which the preparation is packaged, the expected storage conditions, and the intended use and duration of therapy. **GD – Section 6.1** ☐ Substituting an ingredient (even if that includes use of another generic product) requires assignment of a new BUD.
Master formulation records (MFR) are established for each non-sterile compound and are readily retrievable.	☐ Master formulation records must be developed (or obtained and assessed) for **each** non-sterile compound. It must include all necessary information to compound the non-sterile preparation and indicate supporting rationale, references, and the developer of the formula. **Review Section 6.2.1 of the Guidance Document** for a template of a master formulation record.
	☐ Master formulation records must be kept in a format that is readily accessible to non-sterile compounding personnel. **GD – Section 6.2**

	☐ Review the Ontario College of Pharmacists document outlining the difference between a Master formulation record and the Compounding Record **[LINK]**.
Ingredients used for non-sterile compounding are obtained from recognized, reliable sources and are stored under conditions that will preserve quality and purity.	☐ Ingredients must be obtained from recognized and reliable sources. Reasonable measures are to be taken to determine the purity and safety of the ingredients used for non-sterile compounding. **GD – Section 6.3**
	☐ All ingredients (powder, liquids, etc.) that require special precautions when used or stored must be identified. **GD – Section 6.3**
	☐ Ingredients and raw materials must be stored and kept safely under conditions that will preserve their quality as directed by the manufacturer or according to monographs. **GD – Section 6.3**
	☐ Safety data sheets must be kept current and be made available to all personnel involved in non-sterile compounding. **GD – Section 6.3**
The pharmacy keeps a complete compounding record for each individual prescription as well as for non-sterile preparations made in batches.	☐ The pharmacy must keep a compounding record for **each individual prescription**, as well as for non-sterile preparations made in batches, which includes: ➢ the name, lot number, and expiry date of each active ingredient ➢ the quantity required and weighed ➢ the date of preparation ➢ the assigned BUD ➢ the name of the compounder ➢ the person responsible for quality control ➢ the person who approved the preparation, ➢ and reference to the master formulation record for the preparation.
	☐ Quality control procedures or issues are to be documented as appropriate. **GD – Section 6.4**

Personnel behave in a professional manner, following all pertinent policies and procedures.	☐ Personnel must take reasonable measures to ensure hygiene, safety, and to avoid possible contamination during non-sterile compounding. This includes, but is not limited to: ➢ using appropriate Personal Protective Equipment (PPE), ➢ avoiding sources that might contaminate the preparation (e.g. jewelry, food and drink), and ➢ following all pertinent policies. **GD – Section 6.5**
Steps are taken to verify each stage of the process, as well as the final compounded non-sterile preparation.	☐ Each stage of the non-sterile compounding process, in addition to the final product, should be verified. This includes but is not limited to the list of items included on pages 30 to 31 of the **GD – Section 6.6**.
The pharmacy has processes in place to ensure compounded products are labelled and packaged appropriately.	☐ The prescription label (and if necessary, a supplementary label) must identify all active ingredients and the concentration of each active ingredient. **GD – Section 6.7**
	☐ The prescription label (and if necessary, a supplementary label) must include the beyond use date, as well as special storage and handling information if applicable. **GD – Section 6.7**
	☐ The pharmacy must ensure that the packaging, container, storage, and transportation are suitable for the stability of the product and proper patient use. **GD – Section 6.7.3**
The pharmacy has a recall procedure for compounded non-sterile preparations.	☐ The pharmacy must have a recall procedure to identify patients or pharmacies that have received the compounded non-sterile preparation; notify patients or their caregivers of the recall and perform the necessary follow-up if the preparation has been administered. **GD – Section 6.10**

Section 7: Quality Assurance Implementation Timeline Link	
STANDARD	**GUIDANCE**
As part of the pharmacy's overall Quality Management Program, a quality management program for non-sterile compounding is in place	☐ A quality management program must be in place to periodically verify and document that all non-sterile

to verify that all non-sterile compounding activities are being carried out according to the standards.	compounding activities are being carried out according to the Standards. **GD – Section 7**
	☐ Review Table 6 in **Section 7.6 of the Guidance Document** for examples of components of a quality assurance program.

Section 8: Levels of Requirements Implementation Timeline Link	
STANDARD	**GUIDANCE**
The pharmacy meets the requirements for non-sterile compounding (Level A, B, or C) based on the (1) complexity of the preparation as well as (2) risks associated with compounding the preparation.	☐ Level A: the pharmacy must have a separate space designated for non-sterile compounding. **GD – Section 8.1**
	☐ Level B: the pharmacy must have a separate, well-ventilated room, with a larger workspace, greater protection from cross-contamination, and appropriate equipment. The pharmacy may require a ventilated containment device (C-PEC; Containment Primary Engineering Control) when certain powders, aromatic products or hazardous products are compounded. **GD – Section 8.2**
	☐ Level C: the pharmacy must have a separate, well-ventilated room with appropriate air exchange and negative pressure. An appropriate C-PEC must be available for materials being compounded. **GD – Section 8.3**
	☐ Review Table 7 in **Section 8.4 of the Guidance Document** for a summary of requirements for compounding non- sterile preparations.

Section 9: Requirements for Hazardous Preparations Implementation Timeline Link	
STANDARD	**GUIDANCE**

Facilities for the compounding of hazardous non-sterile preparations are designed and built in accordance with the Standards and provincial/territorial and local regulations.	☐ A sink with hot and cold running water is to be available for handwashing, along with an eyewash station and/or other emergency or safety features that meet applicable laws and regulations. Any water sources and drains are to be located at least 1 meter away from a C-PEC. **GD – Section 9.1.1**
	☐ The room used for compounding hazardous non-sterile preparations needing Level C requirements is to have external venting through high-efficiency particulate air (HEPA) filtration. **GD – Section 9.1.1**
	☐ The room used for compounding hazardous non-sterile preparations needing Level C requirements is to have appropriate air exchange (at least 12 air changes per hour [ACPH]). **GD – Section 9.1.1**
	☐ The room used for compounding hazardous non-sterile preparations needing Level C requirements must have negative pressure (–2.5 Pa relative to surrounding areas). **GD – Section 9.1.1**
	☐ The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the hazardous non-sterile compounding area must be smooth, impermeable, free from cracks and crevices, and made of non-shedding material. **GD – Section 9.1.1**
	☐ Controlled rooms must not have windows or doors opening directly to the exterior of the building. Any doors or windows leading to the outside or to a non-controlled area (other than the doors designated for accessing the room) must be sealed. **GD – Section 9.1.3**
	☐ A procedure is established for receiving, unpacking, and storing hazardous products that includes processes for undamaged, sealed/unsealed products as well as for damaged packaging. Refer to Diagram 2 in the **Guidance Document in Section 9.1.4.**

	☐ Hazardous products must be stored in a room with appropriate ventilation and identified with appropriate signage to indicate the presence of hazardous products. See Table 8 in **Section 9.1.5 of the Guidance Document** for required conditions for a hazardous products storage area.
Appropriate equipment is in place for the handling of hazardous products.	☐ The C-PEC is installed in the non-sterile compounding room and should either be externally vented (preferred) or have redundant HEPA filters in a series. **GD – Section 9.2.1**
	☐ Hazardous non-sterile preparations, such as volatile, liquid or powder forms of cytotoxic products, should be compounded inside a C-PEC that provides protection for personnel and the environment (e.g. Class I or II biological safety cabinet, a containment ventilated enclosure (CVE), etc.). **GD – Section 9.2.1**
	☐ The C-PEC must be maintained according to manufacturer's recommendations and records of maintenance should be maintained. **GD – Section 9.2.1**
	☐ All reusable instruments, devices, and accessories used to handle hazardous non-sterile products must be deactivated, decontaminated, and cleaned after each usage. **GD – Section 9.2.2**
	☐ Personal Protective Equipment (PPE) approved for the compounding of hazardous non-sterile preparations must be worn and replaced/discarded at the appropriate intervals during compounding activities.
The pharmacy has procedures in place to ensure that the areas used for compounding of hazardous non-sterile preparations are kept clean.	☐ The room used for compounding of hazardous non-sterile products is to be kept clean at all times, which includes periodic washing of the walls, ceiling, and storage areas. The floors should be washed at least once a day when the room is in use. **GD – Section 9.3**
	☐ The compounding area, equipment, and accessories must be meticulously cleaned immediately after compounding of preparations containing hazardous products or allergenic ingredients; it is strongly recommended that equipment used

	for compounding these classes of ingredients are set aside specifically for these products, or disposable equipment be used, if possible, to reduce bioburden or cross-contamination. **GD – Section 9.3**
	☐ Only trained and qualified cleaning and disinfecting personnel are permitted to clean controlled rooms. **GD – Section 9.3**
	☐ Cleaning personnel must comply with the pharmacy's hand hygiene and garbing procedure before they enter areas reserved for compounding hazardous products to perform housekeeping duties. **GD – Section 9.3.1**
	☐ Safety data sheets for products used in the facility for deactivation, decontamination, and cleaning must be available on site and readily accessible. **GD – Section 9.3.2**
The pharmacy has procedures in place for deactivating, decontaminating, and cleaning in areas reserved for the compounding of hazardous non-sterile preparations.	☐ The work surface of the C-PEC must be deactivated, decontaminated, and cleaned at the intervals listed in **Section 9.3.3 of the Guidance Document.**
The pharmacy has policies and equipment in place to handle incidents and spills involving hazardous products.	☐ Policies and procedures to be followed in case of accidental exposure of personnel to hazardous products must be established. **GD – Section 9.4.1**
	☐ Policies, procedures, and training programs are to be established to prevent spills and to direct the cleanup of hazardous product spills. Adequate training must be provided to employees who clean up spills, including the use of spill kits and appropriate PPE. **GD – Section 9.4.2**
	☐ Spill kits must be available in locations where hazardous products are handled and should be present when transporting hazardous products. The contents of spill kits should be verified regularly and their expiration dates should be checked. **GD – Section 9.4.2**
	☐ Documentation of all spills and the actions taken following the event is to be completed.

Procedures for the destruction and/or disposal of pharmaceutical waste are implemented.	☐ Procedures must be in place for the destruction and/or disposal of pharmaceutical waste in compliance with environmental protection legislation. **GD – Section 9.5**
	☐ All personnel involved in the management of hazardous product waste must receive appropriate training on destruction procedures to ensure their own protection and to prevent contamination of the premises or the environment. **GD – Section 9.5**
	☐ All equipment, products, and vials used in the compounding of hazardous non-sterile preparations are to be discarded in a hazardous waste container. **GD – Section 9.5**
	☐ Waste created during the compounding of hazardous non-sterile preparations is to be placed in a hazardous waste container inside the C-PEC or placed in a sealable plastic bag before removal from the C-PEC and then discarded in a hazardous waste container. **GD – Section 9.5**
	☐ PPE used during the compounding of hazardous products must be discarded into the hazardous waste container. **GD – Section 9.5**
	☐ Bins used for hazardous product waste are to comply with local, provincial, and federal requirements. **GD – Section 9.5**
Controlled areas and C-PEC are certified and verified according to standards.	☐ The controlled room (C-SEC) and C-PEC must be certified at installation and at least every 6 months, or after repairs or relocation. **GD – Section 9.6.1**
	☐ An environmental verification program established is to include verification for chemical contamination by hazardous products on surfaces used for receipt, storage, preparation, and verification of product and preparations. **GD – Section 9.6.3**
	☐ The level of hazardous product contamination should be measured (e.g. wipe sampling) at least once every 6 months, or more frequently if there has been a major change in

	placement of furniture, compounding processes, or cleaning practices. **GD – Section 9.6.3**
	☐ The temperature of controlled rooms is to be monitored and documented at least once a day. **GD – Section 9.6.3**
	☐ Pressure must be measured continuously in the controlled room and an alarm system must be in place to immediately advise personnel of non-compliance with specifications. **GD – Section 9.6.3**
	☐ All completed documentation concerning aspects of testing controlled rooms, the C-PEC, and supporting equipment for hazardous product contamination should be filed and retained.

REFERENCES:

1. Ontario College of Pharmacists (OCP) Non-Sterile Compounding Checklist: https://www.ocpinfo.com/wp-content/uploads/2019/08/2019-07-NSCS-Self-Assessment-Checklist-v4-Fill-Print.pdf
2. Model Standards for Pharmacy Compounding of Non-sterile Preparations
3. Guidance Document for Pharmacy Compounding of Non-sterile Preparations
4. Assessing Knowledge and Technique when Compounding
5. Regulations of the New Brunswick College of Pharmacists (https://nbcp.in1touch.org/document/1733/2015%2007%2023%20REGS%20bilingual.pdf)
6. Policy on Manufacturing and Compounding Drug Products in Canada (https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/policy-manufacturing-compounding-drug-products.html)