Ontario College of Pharmacists
Putting patients first since 1871

# Non-Sterile Preparations Assessment Criteria

The following chart outlines key NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations, 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. Implementation priorities and timelines for completion of each phase are:

- Phase 1: January 1, 2020 – Assessing Risks and Gaps
- Phase 2: July 1, 2021 – Personnel Training and Quality Assurance
- Phase 3: January 1, 2022 – Facilities and Equipment

## Section 2: Objectives and Section 3: Regulatory Framework

| STANDARD | GUIDANCE |
|---|---|
| The pharmacist or pharmacy technician uses an appropriate framework, including 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. **GD – Section 2.1** |
| | ☐ The pharmacist must have an established patient-healthcare professional relationship prior to compounding a non-sterile product for the patient. **GD – Section 3** |
| | ☐ Review the questionnaire in Section 3.1 of the Guidance Document, which provides general guidelines to differentiate between non-sterile compounding and manufacturing activities. **GD – Section 3.1** |
| | ☐ Pharmacy staff should review the Article – Compounding: Are you doing it? (Pharmacy Connection Winter 2018) |
| | ☐ Pharmacy staff should review the Policy on Manufacturing and Compounding Drug Products in Canada (POL-00051) on the Health Canada website. |
| | ☐ The pharmacy must have a process in place to ensure when dispensing a prescriber's order for office use that a valid patient-healthcare professional relationship exists. |
| | ☐ When dispensing a prescriber's order for office use, the pharmacy must have a process in place to ensure the preparation of a compounded product at an appropriate scale, time and frequency. |

| | |
|---|---|
| | ☐ Pharmacy staff should review the Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051) on the Health Canada website. |

## Section 4: Assessing Risk for Compounding Non-Sterile Products

| STANDARD | GUIDANCE |
|---|---|
| A risk assessment is 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, covering risk to preparation and risk to person. Factors to consider include: Complexity of compounding the preparation, need for verification, frequency of compounding, risk of cross- contamination, physical characteristics and quantities of ingredients, facilities and equipment, type of hazardous drug, exposure to compounding personnel, and risk of microbial contamination. **GD – Section 4 / 4.1** |
| | ☐ The risk assessment must be reviewed at least every 12 months to ensure that it is still valid 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 level and requirements for non-sterile compounds. **GD – Section 4.2** |
| | ☐ The requirements for safe non-sterile compounding of all materials should 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 for references for assessing risk. **GD – Section 4.3** |

## Section 5: Requirements for All Levels of Non-Sterile Compounding Activities

| STANDARD | GUIDANCE |
|---|---|
| The Designated Manager or pharmacy department head is responsible for all activities related to non-sterile compounding. | ☐ The Designated Manager or pharmacy department head is responsible for the development, organization and supervision of all activities related to 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** |
| | ☐ 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 staff. Policies and procedures should provide detailed descriptions of all activities, including cleaning. **GD - Section 5.3** |

| | | |
|---|---|---|
| | ☐ | 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, and mixing technique (if applicable), as well as a final check of the finished product, regardless of the individuals preparing the product) including sign off at appropriate intervals. **GD - section 5.2.1.1** |
| | ☐ | Review Sections 5.3.1 and 5.3.2 in the Guidance Document for examples of, and template for, policies and procedures. **GD - section 5.3.1 / 5.3.2** |
| | ☐ | Pharmacy staff should review the ISMP Canada Safety Bulletin - Death Due to Pharmacy Compounding Error *Reinforces Need for Safety Focus* (May 25, 2017) located on the ISMP Canada website. |
| 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. **GD – Section 5.2.1** |
| | ☐ | 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. **GD – Section 5.2.1.1** |
| | | Cleaning personnel must be trained and aware of roles and responsibilities as outlined in Table 2 in Section 5.2.2 of the Guidance Document. **GD– Section 5.2.2** |
| 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 separate space specifically designated for compounding of prescriptions, which should be located away from parts of the pharmacy where there is a considerable amount of traffic and 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 maintained in clean, orderly and sanitary conditions with appropriate and sanitary waste disposal, and shall be maintained in a good state of repair. **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 and efficacy of stored products and to ensure the safety and comfort of non-sterile compounding personnel. Air vents should 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.<br>**GD – Section 5.4.1.4** |
| Equipment, instruments and accessories are appropriate for the type of preparations to be compounded, and are maintained and cleaned. | ☐ | Equipment, instruments and accessories must be appropriate for the type of non-sterile preparations to be compounded, be cleaned after each use, and must not negatively affect the purity or quality of the preparation being compounded. **GD – Section 5.4.2** |
| | ☐ | Equipment, instruments and accessories should be routinely inspected 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 manufacturer recommendations. Records of calibration dates for equipment and instruments must be maintained and be readily retrievable. **GD – Section 5.4.2** |

## Section 6: Product and Preparation Requirements

| STANDARD | | GUIDANCE |
|---|---|---|
| Beyond-use dates are appropriately assigned based on appropriate evidence and literature. | ☐ | Beyond-use dates (BUDs) should be assigned conservatively. **GD – Section 6.1** |
| | ☐ | When assigning beyond-use dates, 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 a manufactured drug is used as the API, information provided by the manufacturer may be used as a reference for assigning beyond-use dates, but the manufacturer's expiry date for the drug should not be used as the beyond-use date for the final preparation. **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** |

| | | |
|---|---|---|
| Master formulation records are established for each non-sterile compound and are readily retrievable. | ☐ | Master formulation records must be developed (or obtained) 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. **GD – Section 6.2.1** |
| | ☐ | Master formulation records must be kept in a format that is readily accessible to non-sterile compounding personnel. **GD – Section 6.2** |
| Ingredients used for non-sterile compounding are obtained from recognized, reliable sources and are stored under conditions that will preserve quality and purity. | ☐ | Ingredients should be obtained from recognized and reliable sources. Reasonable measures should 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 should be identified. **GD – Section 6.3** |
| | ☐ | Ingredients and raw materials should be stored and kept safely under conditions that will preserve their quality and purity as directed by the manufacturer or according to pharmacopeia monographs.<br>**GD – Section 6.3** |
| | ☐ | Safety data sheets must be kept up-to-date 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, including: 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, and the person who approved the preparation; and reference to the master formulation record for the preparation. Quality control procedures or issues should 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 using appropriate personal protective equipment, 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 the formula, calculations, ingredients and their amounts, compounding technique, the compounding record and the master formulation record, the final label, and the final product in its final packaging.<br>**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) should identify all active ingredients and the concentration of each active ingredient.<br>**GD – Section 6.7** |
| | ☐ | The prescription label (and if necessary, a supplementary label) should include the beyond use date, as well as special storage and handling information if applicable.<br>**GD – Section 6.7** |

## Section 7: Quality Assurance

| STANDARD | | GUIDANCE |
|---|---|---|
| A quality assurance program is in place to verify that all non-sterile compounding activities are being carried out according to the standards. | ☐ | A quality assurance program must be in place to periodically verify and document that all non- sterile compounding activities are being carried out according to the Standards.<br>**GD – Section 7** |
| | ☐ | Review Table 6 in Section 7.6 of the Guidance Document for examples of components of a quality assurance program.<br>**GD – Section 7.6** |

## Section 8: Levels of Requirements

| STANDARD | | GUIDANCE |
|---|---|---|
| For compounding areas categorized as Level A: The pharmacy meets the requirements for non-sterile compounding based on the complexity and risks associated with compounding the preparation. | ☐ | The pharmacy must only compound simple or moderate preparations in the Level A designated space –<br>**GD – Section 8.1** |
| | ☐ | The pharmacy must ensure that a level A compounding area is used to prepare simple or moderate preparations containing materials classified as health hazards under the Hazardous Products Act only if these preparations are made in occasional small quantities, have been assessed to pose a low risk to compounding personnel at the specific pharmacy location, and appropriate safety precautions and risk mitigation controls are in place.<br>**GD – Section 8.1** |
| | ☐ | Review Table 7 in Section 8.4 of the Guidance Document for a summary of requirements for compounding non- sterile preparations.<br>**GD – Section 8.4** |

| | | |
|---|---|---|
| For compounding areas categorized as Level B: The pharmacy meets the requirements for non-sterile compounding based on the complexity and risks associated with compounding the preparation. | ☐ | The pharmacy must have a dedicated room that is separate from the rest of the pharmacy to provide a larger work space for compounding complex preparations, storage of materials and equipment, uninterrupted workflow and greater protection from cross-contamination.<br>**GD - Section 8.2** |
| | ☐ | The pharmacy must have a ventilated, entirely closed off room or a room with a ventilated containment device (C-PEC; Containment Primary Engineering Control), which is required for compounding of certain powders, aromatic products and other hazardous products, including allergenic products or products that could have unintended effects, such as hormones, but that may not require the extensive precautions of Level C requirements if prepared in small quantities and risk can be mitigated. If a ventilated containment device is used, the pharmacy should follow the same requirements as outlined in section 9.2.1<br>**GD – Section 8.2** |
| | ☐ | The C-PEC installed in the compounding room must be either be externally vented (the preferred option) or have redundant HEPA filters in a series. The safety cabinet should be chosen according to the volume of preparations and products to be compounded.<br>**GD - Section 9.2.1** |
| | ☐ | The C-PEC must be maintained in accordance with the manufacturer's recommendations. **GD - Section 9.2.1** |
| | ☐ | The C-PEC must be certified at least every 6 months, and during maintenance or repair of equipment that might alter operational parameters<br>**GD - Section 9.6.1** |
| | ☐ | Review Table 7 in Section 8.4 of the Guidance Document for a summary of requirements for compounding non- sterile preparations.<br>**GD – Section 8.4** |
| For compounding areas categorized as Level C: The pharmacy meets the requirements for non-sterile compounding based on the complexity and risks associated with compounding the preparation | ☐ | The pharmacy must have a physically separated room dedicated to compounding, externally ventilated through HEPA filtration, with appropriate air exchange and negative pressure relative to surrounding rooms, and an appropriate containment device (C-PEC) for materials being compounded<br>**GD – Section 8.4** |
| | ☐ | Review Table 7 in Section 8.4 of the Guidance Document for a summary of requirements for compounding non- sterile preparations.<br>**GD – Section 8.4** |

| Section 9: Requirements for Hazardous Preparations | |
|---|---|
| **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 should be available for handwashing, along with an eyewash station and/or other emergency or safety features that meet applicable laws and regulations. Water sources and drains should be located at least 1 meter away from the C-PEC. **GD – Section 9.1.1** |
| | ☐ The room used for compounding hazardous non-sterile preparations needing Level C requirements should 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 should have physical separation from other preparation rooms. **GD – Section 9.1.1** |
| | ☐ The room used for compounding hazardous non-sterile preparations needing Level C requirements should 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 should 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 should 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) should also 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 and damaged packaging. Refer to Diagram 2 in the Guidance Document in Section 9.1.4. **GD – 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. **GD – Section 9.1.5** |

| | | |
|---|---|---|
| Appropriate equipment are 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. **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, as described in Section |
| 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 should be kept clean at all times, which entails 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 should be allowed 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 least daily when in use, after spills, after interruptions, if ventilation is moved, and before starting the compounding of different preparations. **GD– Section 9.3.3** |
| The pharmacy has policies and equipment are 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 and procedures and training programs should be established to prevent spills and to direct the cleanup of hazardous product spills. Adequate training should be provided to employees who clean up spills, including the use of spill kits, and appropriate PPE. **GD – Section 9.4.2** |
| | ☐ | Spill kits should 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 checked. **GD – Section 9.4.2** |
| 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 should be discarded in a hazardous waste container. **GD – Section 9.5** |
| | ☐ | Waste used in the compounding of hazardous non-sterile preparations should 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** |
| | ☐ | All PPE should be discarded into the hazardous waste container. **GD – Section 9.5** |
| | ☐ | Bins used for hazardous product waste should 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 thereafter, or after repairs or relocation. **GD – Section 9.6.1** |
| | ☐ | Manufacturers' factory-issued certificates for all HEPA filters and C-PECs must be retained for the service life of the equipment. **GD – Section 9.6.3** |

| | | |
|---|---|---|
| | ☐ | An environmental verification program established should 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, 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 should be verified and documented at least once a day.<br>**GD – Section 9.6.3** |
| | ☐ | Pressure should be measured continuously in the controlled room, and an alarm system should 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.<br>**GD – Section** |