

## Non-sterile compounding FAQs

### What is the difference between the standards and guidance documents?

Standards establish requirements, using the language of “must.” A regulated member must comply with each standard, and failure to comply with a standard may be considered unprofessional conduct. Guidelines use the language of “should” and establish the professionally accepted means by which regulated members can achieve compliance with the standards. Guidelines are not recommendations; they establish the expected conduct of regulated members.

### How long do I have to meet the new standards at my pharmacy?

The standards will apply to new pharmacies, relocations, and renovations effective immediately, but existing locations have time to comply via the phased implementation plan. All pharmacies must have achieved the standards related to priorities one and two (human factors, risk assessment, personal protective equipment, additional training, etc.) by January 1, 2020. All pharmacies must comply with priority three by July 1, 2021.

### What should I do if I am uncertain about the risk level of a compound?

If there is uncertainty as to the level of risk, then the licensee should defer to the higher standard.

### Are there standardized examples of Level A, B and C compounds?

Conduct a risk assessment for each active pharmaceutical ingredient (API) in each compound that you make at your pharmacy. The risk level requirements depend on the results of your risk assessment. Here are examples of risk assessments for [diclofenac](#) and for [hydrocortisone cream mixed with ketoconazole cream](#).

### How do I determine if a product is listed as a health hazard under the *Hazardous Products Act*? How do I use the product safety data sheet (SDS) to determine the hazards identified with that product?

See schedule 2 under the *Hazardous Products Act* for a [listing of health hazard classes](#).



See the SDS for the active pharmaceutical ingredient (API) to determine any associated health hazard classes. Canada has aligned the Workplace Hazardous Materials Information System (WHMIS) with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). On each SDS, refer to Section 2 - Hazards Identification. A health hazard can be identified with a pictogram (see left). [Click here](#) to learn more.

The licensee must make risk assessments for APIs available to all staff involved in compounding to make sure that they are aware of all possible risks.

### Do you need separate areas for compounding hazardous and non-hazardous non-sterile preparations?

It is preferable to have separate areas for performing hazardous and non-hazardous non-sterile compounding. If the same area is being used for hazardous and non-hazardous non-sterile compounding then separation strategies should be implemented within the area, such as not compounding at the same time and utilizing dedicated or disposable equipment for hazardous compounding whenever possible. After hazardous compound preparation, the compounder must ensure proper deactivation, decontamination and cleaning to prevent cross-contamination.

### **What is the minimum size for a designated Level A compounding area?**

There is no minimum size requirement. The compounding area must be large enough for compounding personnel to work comfortably and safely, with room to store equipment and products in an orderly manner, and in clean and secure surroundings. Also, the area should be designed and arranged to prevent cross-contamination between products, and it should be located away from parts of the pharmacy where there is a considerable amount of traffic (e.g., aisles, entrance, exit).

### **What are the facility requirements for compounding diclofenac gel?**

Diclofenac gel must be compounded in a facility meeting Level B or C requirements, depending on the licensee's risk assessment. If the licensee determines that the site compounds diclofenac gel in occasional, small quantities, Level B requirements may be sufficient. Conversely, if the site compounds diclofenac gel frequently, in larger quantities, then the licensee should defer to Level C requirements. If in doubt, defer to the higher standard. As per the Guidance Document for Pharmacy Compounding of Non-sterile Preparations, Section 4.1, some factors to consider in the risk assessment include the

- complexity of compounding the preparation;
- need for verification and uninterrupted workflow;
- frequency of compounding high-risk or low-risk preparations;
- risk of cross-contamination with other products (e.g., allergens);
- concentration of ingredients in the product;
- quantity of ingredients being handled;
- physical characteristics of ingredients (e.g., liquid vs. solid vs. powders, or water-soluble vs. lipid-soluble);
- education and competency of compounding personnel;
- availability of appropriate facilities and equipment;
- classification of ingredients if identified by WHMIS as presenting a health hazard, or a drug classified by NIOSH as hazardous (see reference to NIOSH in section 4.3);
- type of hazardous drug (e.g., anti-neoplastic, non-antineoplastic, reproductive risk only);
- exposure to compounding personnel for each preparation and accumulation of exposure over time; and
- risk of microbial contamination (liquids, creams, and ointments may be particularly susceptible to microbial and other contamination).

The risk assessment must be reviewed on a continuum to identify and mitigate risk, thereby providing quality assurance.

A decision algorithm to assist in determining requirements for non-sterile compounding can be found in the Guidance Document for Pharmacy Compounding of Non-sterile Preparations, Section 4.2.

**Note:** Occasional small quantities of materials must not be considered in isolation. If several different high-risk or low-risk preparations are being compounded, the cumulative risk must be considered even if they are compounded on different days. This must be documented in the risk assessment. Licensees must avail an environment and equipment that ensures the safety of pharmacy personnel when evaluating level of risk. If there is uncertainty as to the level of risk, then the licensee shall defer to the higher standard.

## **Would current computer-generated compounding work sheets satisfy the requirements of Master Formulation Records and ongoing compounding records?**

See section 6.2 of the Guidance Document for Pharmacy Compounding of Non-sterile Preparations for the requirements of a Master Formulation Record. The development of a new Master Formulation Record is based on scientific data and includes appropriate references. The Master Formulation Record for a non-sterile preparation includes all necessary information to compound the preparation. To ensure preparation quality and safety, the Master Formulation Record should be current. Changes made in the Master Formulation Record should include supporting rationale and references, and compounding personnel must be informed of the change. Computer-generated mixture instruction sheets may be used, provided they meet documentation requirements as outlined in section 6.2 of the Guidance Document for Pharmacy Compounding of Non-sterile Preparations.

Master Formulation Records should be kept together, in hard copy or electronic format, and be readily available.

In addition, each time a non-sterile compound is prepared for individual prescriptions or batches, a compounding record must be created that meets the requirements outlined in Standard 10.11 of the Standards of Practice for Pharmacists and Pharmacy Technicians.

### [Master Formulation Record vs Compounding Record](#)

## **How do I determine what ventilation is needed for non-sterile compounding?**

The licensee must determine what ventilation is required for both the compounding room, as well as for the containment primary engineering control (C-PEC) through their risk assessment. All risk assessments must be made available to staff involved in compounding.

External ventilation is not required for a designated and separate compounding area for Level A compounded preparations. For Level B compounded preparations, the room must be separate, with a door, and well-ventilated. A well-ventilated room meets the following requirements:

- Maintains staff comfort when wearing PPE.
- Prevents cross-contamination between different compounded products being compounded in the same room .
- Includes heating, ventilation and air conditioning systems that are controlled to avoid decomposition and contamination of chemicals, to maintain the quality of products, and to ensure the safety and comfort of compounding personnel.
- Does not have air vents located directly over work areas.
- Prevents exposure of staff in the room to particles generated during compounding.
- Ventilation must occur through a professional, engineered design HVAC system. Window ventilation or portable fans are not acceptable.

A Level B room must be internally ventilated using high-efficiency particulate air (HEPA) filtration or externally ventilated with or without HEPA filtration. The decision to install external ventilation for a Level B room depends on many factors, including the types and quantities of compounds prepared and the ventilation provided by an externally ventilated C-PEC in the room. External ventilation of the room with HEPA filtration should be considered when potentially hazardous compounds are compounded, even in small quantities.

When complex and small quantities of ingredients requiring ventilation are prepared in a Level B room (certain powders, aromatic products and hazardous products) a ventilation containment device (C-PEC) is needed.

The room used for compounding Level C hazardous preparations must meet the following requirements:

- External ventilation through HEPA filtration.
- Physical separation from other preparation rooms.

- Appropriate air exchange of at least 12 air changes per hour (ACPH).
- Negative pressure (–2.5 Pa relative to surrounding areas).

If a C-PEC is installed in a Level B or C compounding room, then it should either be externally ventilated (the preferred option) or have redundant HEPA filters in a series. Redundant HEPA filters in a series may be appropriate for a compounding pharmacy where small quantities of hazardous products with low safety risks are being compounded, or where external ventilation is already provided through secondary engineering controls (room ventilation).

**What are the requirements for eye wash stations?**

Compounding areas must contain an eyewash station and other emergency or safety equipment as determined by the risk assessments completed for the compounds prepared. Licensees should also determine the type of eyewash station that is appropriate based on their non-sterile compounding risk assessment.

**What are the requirements for the distance of a sink and heat source to a designated compounding area?**

For Level A compounding, the sink with hot and cold running water must be available in or reasonably close to the compounding area. For Level B and Level C compounding, the sink must be located in the compounding room, and the sink should be at least 1 metre away from the C-PEC.

For Level A, B, and C compounding, the heat source must be located in the compounding area or room.

**What are the requirements in regard to safety showers?**

The need for a safety shower will be determined through your risk assessment.

**What are the external ventilation requirements for dedicated storage areas of hazardous compounds?**

Hazardous products, particularly antineoplastics, should be grouped and stored in a properly ventilated room with all air exhausted to the exterior. The storage area should have negative pressure (-2.5 Pa) relative to the adjacent rooms and should have at least 12 air changes per hour (ACPH). The storage area should be identified with appropriate signage (section 9.1.6 of the Guidance Document for Pharmacy Compounding of Non-sterile Preparations) to indicate the presence of hazardous products.

For non-antineoplastics, products that carry a reproductive risk, and final dosage forms, external ventilation is recommended, but this may not always be possible.

**What is a small quantity?**

Small quantity depends on the risk assessment for each API which should include an assessment of frequency of compounding with these ingredients. As per the Guidance Document for Pharmacy Compounding of Non-sterile Preparations, Section 4.1, some factors to consider in the risk assessment include the

- complexity of compounding the preparation;
- need for verification and uninterrupted workflow;
- frequency of compounding high-risk or low-risk preparations;
- risk of cross-contamination with other products (e.g., allergens);
- concentration of ingredients in the product;
- quantity of ingredients being handled;
- physical characteristics of ingredients (e.g., liquid vs. solid vs. powders, or water-soluble vs. lipid-soluble);
- education and competency of compounding personnel;
- availability of appropriate facilities and equipment;

- classification of ingredients if identified by WHMIS as presenting a health hazard, or a drug classified by NIOSH as hazardous (see reference to NIOSH in section 4.3);
- type of hazardous drug (e.g., anti-neoplastic, non-antineoplastic, reproductive risk only);
- exposure to compounding personnel for each preparation and accumulation of exposure over time; and
- risk of microbial contamination (liquids, creams, and ointments may be particularly susceptible to microbial and other contamination).

The risk assessment must be reviewed on a continuum to identify and mitigate risk thereby providing quality assurance.

A decision algorithm to assist in determining requirements for non-sterile compounding can be found in section 4.2.

Note: Occasional small quantities of materials must not be considered in isolation. If several different high-risk or low-risk preparations are being compounded, the cumulative risk must be considered even if they are compounded on different days. This must be documented in the risk assessment. Licensees must avail an environment and equipment that ensures the safety of pharmacy personnel when evaluating level of risk. If there is uncertainty as to the level of risk, then the licensee shall defer to the higher standard.

**Can a pharmacy order a bulk compound from a compounding and repackaging pharmacy and modify the compound's concentration?**

No. Modifications to compounds obtained through a compounding and repackaging agreement would be considered manufacturing.