Ontario College of Pharmacists
Putting patients first since 1871

This example is for illustrative purposes only; it is not directing you to a specific course of action, is not to be construed as legal advice or opinion, and is not to be taken as a position of the Ontario College of Pharmacists. While every effort will be made to ensure these examples are up to date, you must use your own professional knowledge, skills, and judgment when completing your own risk assessments and defer to the most recent guidance, references, and resources.

Non-Sterile Compounding Risk Assessment Template[1]

This tool has been published in conjunction with a companion guide – a resource intended to assist registrants' understanding of what to document, reference, and consider when determining the appropriate level of requirements for each preparation compounded at your pharmacy. Use of this form is optional. How a pharmacy chooses to document risk assessments is at the discretion of the Designated Manager or the compounding supervisor.

Complete one risk assessment for each compounded preparation.

1. **Preparation name:** Progesterone 400 mg suppository

A. Identify the risk(s)

2. List the following for all ingredients used in the preparation, including drugs, and active pharmaceutical ingredients (APIs). Attach safety data sheets (SDSs) if available.

Name	Manufacturer	DIN or CAS#	Physical Characteristics*	References
Progesterone, USP (wettable)	PQR Chemicals	CAS#000-000-1	Powder	☒ SDS ☐ Monograph
Fatty acid base	PQR Chemicals	CAS#000-000-2	Solid	☒ SDS ☐ Monograph
Silica gel	PQR Chemicals	CAS#000-000-3	Powder	☒ SDS ☐ Monograph

**Physical characteristics: liquid, volatile liquid, semi-solid, solid, solid powder, cream/ointment, etc.*

3. Are any of the above in the *NIOSH List of Hazardous Drugs in Healthcare, 2024?*

☐ No

☒ Yes → Check all that apply and specify which ingredients in the space provided:

☐ **Table 1 (hazardous drugs with carcinogenic properties):**
☒ **Table 2 (other hazardous drugs):** Progesterone

[1] Source: Saskatchewan College of Pharmacy Professionals non-sterile compounding risk assessment template. Adapted with permission.

4. Are any of the above identified by WHMIS information as presenting a health hazard (as per section 2 of the safety data sheets [SDSs])?

☐ No
☒ Yes → Specify which ingredients, and describe the health hazard(s):

Progesterone
Acute toxicity – oral (Category 5)
Toxic to reproduction (Category 1B)
Carcinogenicity (Category 1B)
May be harmful if swallowed
May damage fertility or the unborn child
May cause cancer

Fatty acid base
As per the SDS: "Based on available data, the classification criteria are not met"

Silica gel
As per the SDS: "Based on available data, the classification criteria are not met"

5. Does NIOSH, WHMIS information (e.g., as per the SDSs), or product monograph(s) indicate that any of the ingredients:

a) Require ventilation for preparation?

☐ No/ not applicable
☒ Yes → Specify which ingredients and describe the risks:

Progesterone:
Adequate mechanical ventilation required (fume hood) (SDS section 8)
May be harmful if inhaled. May cause respiratory tract irritation (SDS section 11)

b) Present a reproductive risk to the compounder (if not already specified in question #4)?

☐ No / not applicable
☒ Yes → Specify which ingredients and describe the risks:

Progesterone:
As per SDS section 11, may damage fertility or the unborn child
NIOSH Table 2

c) Present any other potential risks to the compounder (i.e., any warnings or precautions)?

☐ No/ not applicable
☒ Yes → Specify which ingredients and describe the potential risks:

Progesterone:
As per SDS section 2, Acute Toxicity - Oral (Category 5)

6. Is there a risk of the following when compounding this preparation (check all that apply):

- ☒ Microbial contamination
- ☒ Cross contamination with other products or preparation(s)
- ☒ Interruption to your workflow
- ☐ Other risk(s); please specify (see NAPRA GD 4.1):

B. Assess the risk(s)

7. What quantity of this preparation is being compounded at a time (average?)

60 suppositories

8. How often is this preparation compounded?

☐ Daily ☒ Weekly ☐ Monthly ☐ Other, please specify:

9. Based on the previous two questions, would you consider this to be an "occasional small quantity"?

- ☒ No
- ☐ Yes → Please outline your rationale, including consideration of *cumulative risk*:

10. What facilities and equipment are necessary to compound this preparation?

We have a compounding room (C-SEC) that meets the requirements for Level C compounding; all finishes of the room meet requirements for hazardous compounding (floor, wall, ceilings).
Additional details and features present:

- External venting through HEPA filtration
- Appropriate air exchange (12 ACPH)
- Negative pressure (–2.5 Pa relative to surrounding areas)
- Surfaces of ceilings, walls, floors, fixtures, shelving, counters and cabinets in the non-sterile compounding area are smooth, impermeable, free from cracks and crevices, and made of non-shedding material
- Eyewash station
- Spill kit (as per ASSTSAS)

Within the C-SEC, we have a C-PEC that is externally vented (Class I Biologic Safety Cabinet).
We also have some separate equipment that is designated for hazardous compounding:

- Beaker
- Hot plate and magnetic stirrer
- Mortar and pestle
- Suppository mold
- Spatula

11. Is additional training required to compound this preparation?

☐ No

☒ Yes → Describe the requirements needed:

In addition to general compounding competence, the compounder should also have specialized knowledge in: - Education/training on hazardous compounding (protocols, handling of APIs, cleaning procedures, donning/doffing PPEs, spill handling and waste management, facility and environmental monitoring) - Preparation of suppositories

12. Based on the previous two questions, what is the complexity of this preparation?

☐ Simple ☐ Moderate ☒ Complex

Please outline your full rationale:

- Specialized facilities (e.g., C-SEC) and equipment (e.g., C-PEC) are required to minimize contamination of the hazardous non-sterile preparation and to provide adequate protection for personnel - Specialized training is required for compounding suppositories, including using the facilities and equipment

C. Mitigate the risk(s)

13. What personal protective equipment (PPE) is required to compound this preparation*?

PPE	Required	Type (please be specific)
Eye protection	☒ Yes ☐ No	Goggles
Mask / respirator	☒ Yes ☐ No	Fit-tested N95 mask
Face protection	☐ Yes ☒ No	
Gloves	☒ Yes ☐ No	Two (2) pairs of chemotherapy gloves meeting the ASTM International standard D6978 (or its successor)
Gown / lab coat	☒ Yes ☐ No	Disposable hazardous gown, closed in the back
Other PPE, please specify:	☒ Yes ☐ No	Hair net, shoe covers

**See question 4 and consider potential routes of exposure such as skin, eye, inhalation, oral, etc.*

Note: Surgical masks do not provide respiratory protection against drug exposure and should not be used when respiratory protection against hazardous drug exposure is required (see NAPRA guidance document, section 9.2).

IF APPLICABLE:

14a. How is the ventilation required for compounding this preparation being achieved*?

Prepared inside externally vented C-PEC, which is located inside the room that meets Level C requirements

See question 5a.

14b. How is the reproductive risk to compounding personnel being mitigated*?

- Prepared inside externally vented C-PEC, which is located inside the room that meets Level C requirements - Hazardous PPE required

See question 5b.

14c. How other risks to compounding personnel being mitigated*?

- Prepared inside externally vented CPEC, which is located inside the room that meets Level C requirements - Hazardous PPE - Deactivation of all equipment performed inside of CPEC (e.g., beakers, spatula, suppository mold)

See question 5c.

15. Describe what measures you will implement to mitigate the risks below*:

Risk	Risk Mitigation Measure(s)
Microbial contamination	Maintaining a clean and sanitary compounding area, including proper cleaning of compounding equipment and all surface areas
Cross contamination	Perform full deactivation and decontamination of, and cleaning procedures for, surfaces, equipment, and C-PEC each time a preparation is compounded Use dedicated equipment for hazardous compounding
Interruption to your workflow	Separate room for compounding, dedicated compounder (not using dispensary staff)
Other risk(s):_____	

See question 6.

D. Risk assessment – result

16. Level of risk assigned for compounding this preparation:

☐ Level A ☐ Level B ☒ Level C

17. Outline your rationale for the level of risk assigned and describe the level of requirements that must be in place to compound this preparation:

Based on the hazards associated with APIs, and the specialized education and training required to prepare this complex compound, this compound requires:

- Compounding room that meets Level C requirements
- C-PEC that is externally vented
- Dedicated hazardous equipment and PPE
- Education/training for compounders for hazardous compounding

E. Sign off

Date completed: February 5, 2026

Date last reviewed: N/A (to be reviewed annually, or sooner if needed)

Name of compounding personnel completing the risk assessment: Ari Singh

Name of non-sterile compounding supervisor: Ren Silva

Signature of non-sterile compounding supervisor: *Ren Silva*