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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:

Affix **or** upload sample label below and/or specify pseudo-identification number (PIN), if available (optional):

Affix label here	**Upload image**

A. Identify the risk(s)

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

Ingredient	Manufacturer	DIN or CAS#	Physical Characteristics*	References
				☐ SDS ☐ Monograph
				☐ SDS ☐ Monograph
				☐ SDS ☐ Monograph
				☐ SDS ☐ Monograph

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

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

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):**

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):

5. Does the 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:

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

☐ No / not applicable
☐ Yes → Specify which ingredient(s) and describe the risks:

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

☐ No / not applicable

☐ Yes → Specify which ingredient(s) and describe the potential risks:

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); Specify below (see NAPRA GD 4.1):

B. Assess the risk(s)

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

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 → Outline your rationale, including consideration of *cumulative risk*:

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

11. Is additional training required to compound this preparation?

☐ No
☐ Yes → Describe the requirements needed:

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

☐ Simple ☐ Moderate ☐ Complex

Outline your full rationale:

C. Mitigate the risk(s)

13. What personal protective equipment (PPE) is required for compounding this preparation*?

PPE	Required	Type (please be specific)
Eye protection	☐ Yes ☑ No	
Mask / respirator	☑ Yes ☐ No	
Face protection	☑ Yes ☐ No	
Gloves	☐ Yes ☑ No	
Gown / lab coat	☑ Yes ☐ No	
Other PPE, please specify:	☐ Yes ☑ No	

**See question 4 and consider all 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*?

See question 5a.

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

See question 5b.

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

See question 5c.

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

Risk	Risk Mitigation Measure(s)
Microbial contamination	
Cross contamination	
Interruption to your workflow	
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:

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E. Sign off

Date completed:

Date last reviewed:

Name of compounding personnel completing the risk assessment:

Name of non-sterile compounding supervisor:

Signature of non-sterile compounding supervisor:

SAVE AS PRINT CLEAR FORM