

NON-STERILE COMPOUNDING RISK ASSESSMENT FORM

Compound: _____

Consider active pharmaceutical ingredients (APIs) and attach Safety Data Sheets (SDSs) if available

_____ DIN _____ SDS Yes No Manufacturer: _____

_____ DIN _____ SDS Yes No Manufacturer: _____

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NIOSH Classification? Yes No

Table 1 Table 2 Table 3

Is this toxic to Reproduction? Yes No

WHIMIS Health Hazard? Yes No

Description (as per Section 2 of SDS_Safety Data Sheet):

Product monograph contraindications, warnings or precautions:

Complexity of this compound (as per USP 795): Simple Moderate Complex

Is this compound only prepared occasionally? Yes No

Describe how often this compound is prepared e.g. daily, weekly, monthly, etc.: _____

Are there only small quantities of ingredients being prepared? Yes No

On average, what quantity of this preparation is being prepared at a time? _____

Do the concentrations of ingredients in the product present a health risk to the compounder? Yes No

Physical characteristics of the ingredients:

Liquid Volatile Liquid Semi-Solid Solid Powder Cream/Ointment

Does the preparation require special education or competencies for your compounding personnel?

Yes No

If yes, then describe this in a master formulation record and consider whether level B or C requirements apply (see Master Formulation).

Are there verification steps during compounding? Yes No

Do you have appropriate facilities and equipment to prepare this compound? Yes No

Is ventilation required for preparation (as per section 8 of SDS or product monograph)?

SDS: Yes No / Product Monograph: Yes No

Is your workflow uninterrupted? Yes No

If no, describe your processes to address the situation in order to meet standards:

Is there a risk of microbial contamination? Yes No

Is there a risk of cross contamination with other products? Yes No

Exposure risk to compounding personnel (as per section 2 of the SDS or product monograph):

From SDS

SKIN: Yes No EYE: Yes No INHALATION: Yes No ORAL: Yes No

Other: _____

From Product Monograph

SKIN: Yes No EYE: Yes No INHALATION: Yes No ORAL: Yes No

Other: _____

Personal Protective Equipment (PPE) deemed necessary (as per the SDS, product monograph and assessment of risk):

GLOVES: Regular Chemotherapy Double Gloves

COMPOUNDING JACKET/GOWN: Designated compounding jacket Disposable hazardous gown

MASK: Yes No Type _____

EYE PROTECTION: Yes No

OTHER PPE necessary (e.g. head, hair or shoe covers, etc.): _____

Is an eye-wash station required? Yes No

Is a safety shower required? Yes No

Risk Level Assigned: Level A Level B Level C

Rationale and other risk mitigation measures:

Compounding Supervisor (First Name/Last Name): _____

Signature: _____ Date(dd/mm/yyyy): ___/___/_____