Risk Assessment

Risk assessment must be performed and documented for each instance of compounding, including repeat prescriptions. Risk assessment must address:

- Risk to patient (ex: is patient pregnant or breastfeeding? Do they have documented allergies?)
- Formulation related risk (ex: wholesaler is unable to supply material)
- Risk to personnel (ex: staff is not suitable trained)
- Risk to premises (ex: starting material is hazardous)
- Regulation related risk (ex: commercially available alternative is available)

For each type of risk, the compounder must document what the source of the risk is (see the examples listed above), what is being done to mitigate the risk, the likelihood of the risk (rated on a scale of A to D, A being 'almost certain' and D being 'unlikely'), and the consequence of the risk on a scale of 1 to 4) (1 being severe, 4 being insignificant). A risk rating is assigned based on a combination of the likelihood of the risk occurring and the consequence of the risk:

Likelihood of risk	Consequence of Risk			
	4 (not significant)	2 (minor)	2 (major)	1 (severe)
A (almost certain)	LR	MR	HR	ER
B (Likely)	LR	MR	HR	ER
C (Possible)	LR	MR	HR	ER
D (Unlikely)	LR	LR	MR	HR

Extreme risk (ER): Do not compound: contact prescriber.

High risk (HR): Seek expert guidance before compounding, or refer to alternative provider with expertise.

Medium risk (MR): Exercise caution when compounding (ensure risk mitigation strategies are in place).

Low risk (LR): Compound in accordance with best practice.

Based on risk category, minor or significant interventions may be necessary. Minor interventions include things like the need for PPE (face mask/gloves) to reduce risk to personnel, significant interventions include things like requirements for additional training or specialist equipment.

Preparation:			
Date:			
Is there a suitable commercially available product?	Yes No (circle one)	Comment:	
Is there a suitable commercially available alternative?	Yes No (circle one)	Comment:	
Is it possible to use an existing pharmaceutical formula?	Yes No (circle one)	Comment:	
What are the risks associated with compounding this preparation	Comment:		
Patient related risk factors (pregnancy/allergies/age etc.)	Source of Risk and Mitigations:	Likelihood (A-D) and Consequence (1-4)	Risk Rating:
Formulation-related risk factors (wholesaler unable to supply, starting material discontinued)			
Personnel-related risk (inadequate training)			
Premises-related risk (hazardous material: teratogenic, cytotoxic etc.)			
Regulation-related risk (is there a suitable commercially available medicine?)			
Overall Risk Rating			
Decision to Compound (note, if risk rating is “ER” compounding is not acceptable)	Yes No (circle one)		
Signature		Date	