Risk Assessment Tool: Preparation of Injectable Medicines

*****Before using the tool users please read the supporting information**
Assessing risks when reconstituting injectable medicines (SPS page)***

Name and strength of prepared medicinal product:
Hospital site:
Diluent:
Final volume:
Pre-preparation storage condition and expiry:
Date of assessment:
Bag, syringe, other (please specify):
Post preparation storage condition and expiry:

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	Risk factors	Description of individual risks	Allocated score	Score if applicable
1	Therapeutic risk	There is a significant inherent risk of patient harm if the injectable medicine is not prepared and/or administered as intended. (see notes page 5)		**1**
2	High risk route of administration	Examples include intra-ocular, intrathecal, intracerebral, epidural, intraosseous etc.		**10**
	Use of a concentrate	Where further dilution after first reconstitution is essential for safe administration use, i.e. when slow iv injection of undiluted medicine is not appropriate and/or potentially harmful (see notes page 5)		3
4	Complex calculation	Any calculation with more than one step required for preparation and/or administration		**1**
5	Complex method	Complex preparation method - tick all in the list below that apply	**N/A**	**N/A**
5.1	Complex method	Greater than 5 non-touch aseptic manipulations		**1**
5.2	Complex method	Syringe-to-syringe transfer		**1**
5.3	Complex method	Use of a burette admin set		**1**
5.4	Complex method	Any other “open system” manipulations such as use of ampoules (higher risk of microbial contamination than vials)		**1**
5.5	Complex method	*Mandatory* removal of fluid from infusion container		**1**
5.6	Complex method	Preparation does not follow SmPC exactly e.g. use of an alternative diluent or method		**5**
5.7	Complex method	Multiple preparations needed to administer a single “dose” because the shelf-life of the infusion is shorter than 24 hours, or less than the expected duration of infusion		**1**
6	Reconstitution of powder in a vial	Where a dry powder must be reconstituted with a liquid solvent		**1**
7.1	Use of a part vial or ampoule, or use of more than one vial or ampoule	Part vial/ampoule		**1**
7.2	Use of a part vial or ampoule, or use of more than one vial or ampoule	2-4 vials/ampoules		**2**

7.3	Use of a part vial or ampoule, or use of more than one vial or ampoule	5-10 vials/ampoules		**4**
7.4	Use of a part vial or ampoule, or use of more than one vial or ampoule	11-20 vials/ampoules		**5**
8	Use of an infusion pump	Tick all that apply	**N/A**	**N/A**
8.1	Use of an infusion pump	All infusion pumps require some element of calculation and therefore have potential for error and should be included in the risk factors. However this potential risk is considered less significant than the risks associated with not using a pump when indicated.		**1**
8.2	Use of an infusion pump	Use of an elastomeric infusion device at near-body temperature		**2**
9	Use of any administration set or other device with which staff may not be familiar	Examples include: empty infusion bag, light protected, low adsorption, non-PVC administration set, set with non-standard in-line filter or air inlet		**1**

Add all risk scores together and determine total risk rating

Total risk score	

Risk Score less than 6	Low Risk: Proposed method/ arrangements have controlled the risks to acceptable levels and preparation can proceed as assessed once assigned actions are complete.	☐
Risk Score 6 to 8	Medium Risk: Proposed method/arrangements control some risks, but residual risks remain. Preparation may proceed as assessed after introduction of assigned actions. Additional mitigation should be considered where possible to further reduce these risks. Where the risk points come from multiple starting containers (i.e. vials), these cannot be mitigated in a clinical area, and preparation in pharmacy is recommended.	☐
Risk Score greater than 8	High Risk: Despite proposed method/arrangements, the risk remains high. To proceed with preparation the organisation must fully understand and accept the risks and must ensure that all proposed mitigations are implemented. Written justification must be documented and an entry in the organisation's risk register should be made. Regular review of the process is required to identify further risk reduction opportunities. Where the risk points come from multiple starting containers, use of elastomeric device at near body temperature and/or doesn't exactly follow the SmPC, these risks cannot be mitigated in a clinical area, and preparation in pharmacy is recommended.	☐

Risk assessment undertaken by: (appropriately experienced nurse/clinician and pharmacist)

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Pharmacist Name		**Clinician Name:**	
Signature		**Signature**	