

### Product specification: Streptozocin 250ml infusion bags

	Name of product	Streptozocin infusion. Aseptically prepared from licensed sterile starting materials. N.B. Streptozocin isn't currently licensed in the UK, but it is licensed in other countries. Assurance should be provided that GMP regulatory standards in the country of origin are equivalent to those that apply in the UK.
	Concentration	Concentration range typically up to 8mg/ml in 250ml infusion bags in accordance with the national dose banding tables. The Streptozocin concentrate should be added to the bag without withdrawal of equivalent volume of Sodium Chloride 0.9% w/v Infusion unless withdrawal of some infusion fluid is required to accommodate the total dose.
	Diluent	Sodium Chloride 0.9% w/v
	Volume	250ml
	Final container	Non-PVC e.g. polyolefin infusion bag with additive port cover. <i>Ideally infusion bag design will incorporate self sealing giving port to minimise H&amp;S risks associated with accidental spillage during administration.</i>
	Starting materials	Licensed Streptozocin powder for reconstitution for injection (see above) Licensed Sodium Chloride Injection 0.9% w/v Licensed Sodium Chloride 0.9% w/v Infusion bags
	Labelling	Labelling must be compliant with the principles of labelling for safety and the BP General specification on unlicensed medicines. There is no requirement for Tall Man lettering for the drug name.
	Label sample	<p>An example label is provided below stating the minimum requirements only (the label format is not restrictive and suppliers can use their preferred layout):-</p> <div style="border: 1px solid black; padding: 10px; text-align: center;"> <p>Streptozocin xxxmg in xxxml Sodium Chloride 0.9% w/v For Intravenous Infusion Infuse the entire contents of the bag</p> <p>Store in a Refrigerator at 2-8°C    Protect From Light Expiry: dd/mm/yyyy                      BN: XXXXXXXXX Keep out of the reach and sight of children Manufacturer's details                      MS XXXXXX <i>Caution Cytotoxic: Handle with care</i></p> </div>
	Batch Number	All products will have a unique batch identification number
	Latex status of - components - manufacturing process	All materials and manufacturing processes will be latex free or clearly labelled if not.
	Stability	Stability studies should conform to the Standard Protocol for deriving and assessment of stability of Aseptic preparations (small molecules) published by the NHS Pharmaceutical QA Committee (4th Edition, April 2017).