NHS England

Product specification: Gemcitabine 250ml infusion bags

	Name of product	Gemcitabine infusion. Aseptically prepared from licensed sterile starting materials.
	Concentration	Concentration range typically up to 10mg/ml in 250ml infusion bags in accordance with the national dose banding tables. Higher concentrations possible if supported by stability data. The Gemcitabine concentrate should be added to the bag without withdrawal of equivalent volume of Sodium Chloride 0.9% w/v Infusion unless withdrawal of some
	Diluent	Sodium Chloride 0.9% w/v
	Volume	250ml - majority of doses will be stable in this volume N.B. Licensed 10mg/ml infusion bags are available (1200mg, 1600mg, 1700mg, 1800mg, 2000mg & 2200mg)
	Final container	Non-PVC e.g. polyolefin infusion bag with additive port cover. *Ideally infusion bag design will incorporate self sealing giving port to minimise H&S risks associated with accidental spillage during administration.*
	Starting materials	Licensed Gemcitabine Injection (38mg/ml, 40mg/ml & 100mg/ml) 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.Tall Man lettering must be used for the drug name.
	Label sample	An example label is provided below stating the minimum requirements only (the label format is not restrictive and suppliers can use their preferred layout):- GEMcitabine xxxxmg in xxxml Sodium Chloride 0.9% w/v For Intravenous Infusion Infuse the entire contents of the bag Check the solution is free from particles before administering Store at Room Temperature Protect From Light Expiry: dd/mm/yyyy BN: XXXXXXXXX Keep out of the reach and sight of children Manufacturer's details MS XXXXXX *Caution Cytotoxic: Handle with care* .
	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).