NHS England

Product specification: Fluorouracil 1000ml infusion bags

	Name of product	Fluorouracil infusion. Aseptically prepared from licensed sterile starting materials.
	Concentration	Concentration range 1mg/ml to 10mg/ml in 1000ml infusion bags in accordance with the national dose banding tables. The Fluorouracil 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 accomodate the total dose.
	Diluent	Sodium Chloride 0.9% w/v
	Volume	1000ml - majority of doses will be stable in this volume
	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 Fluorouracil 25 or 50mg/ml solution for Injection to allow centres to continue using their preferred strength 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	An example label is provided below stating the minimum requirements only (the label format is not restrictive and suppliers can use their preferred layout):- . Fluorouracil xxxmg in xxxxml 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).