NHS England

Product specification: Topotecan 50ml, 100ml, 250ml & 500ml infusion

	Name of product	Topotecan infusion. Aseptically prepared from licensed sterile starting materials.
	Concentration	Concentration range 10 to 50 micrograms/ml in infusion bags in accordance with the national dose banding tables. The Topotecan 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	0.52mg to 2.4mg in 50ml (51ml to 52ml including rounded addition volume) 2.6mg to 5mg in 100ml (103ml to 105ml including rounded addition volume) 5.5mg to 13mg in 250ml (256ml to 263ml including rounded addition volume) 14mg to 24mg in 500ml (514ml to 524ml including addition 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 Topotecan 1mg/ml solution for Injection or powder for reconstitution for injection 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):- TOPotecan xxmg in xxxml Sodium Chloride 0.9% w/v For Intravenous Infusion Infuse the entire contents of the bag Store in a Refrigerator at 2-8^{O}C 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).