NHS England

Product specification: Doxorubicin Liposomal 250ml & 500ml infusion

	Name of product	Doxorubicin Liposomal infusion. Aseptically prepared from licensed sterile starting materials.
	Concentration	Doses as stated under volume below in infusion bags in accordance with the national dose banding tables. The Doxorubicin Liposomal concentrate should be added to the bag without withdrawal of equivalent volume of Glucose 5% w/v Infusion unless withdrawal of some infusion fluid is required to accomodate the total dose.
	Diluent	Glucose 5% w/v
	Volume	up to 82mg in 250ml (up to 291ml including addition volume) 90mg to 150mg in 500ml (545ml to 575ml 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 Doxorubicin Liposomal 2mg/ml solution for injection Licensed Glucose 5% 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. NB: The brand name must be included on the label to distinguish from the non-liposomal product.
	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):- DOXOrubicin Liposomal (Caelyx®) xxxmg in xxxml Glucose 5% 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).