Product specification: Fludarabine pre-filled syringes

	Name of product	Fludarabine injection. Aseptically prepared from licensed sterile starting materials.
	Concentration	Concentration typically up to 12mg/ml in pre-filled syringes with all doses diluted to a final volume of 10ml
	Diluent	Sodium Chloride 0.9% w/v
	Volume	Dose specific volumes in accordance with the national dose banding tables with all doses diluted to a final volume of 10ml
	Final container	Polypropylene or polycarbonate sterile luer lock syringe, graduated in millilitres and sealed with sterile syringe cap/hub. Syringe and syringe cap/hub integrity to be validated. The validation should conform to the Protocols for the integrity testing of syringes published by the NHS Pharmaceutical QA Committee (2nd Edition, April 2013). Air bubbles within the final product must be minimised so the end user can use without need to remove air.
	Starting materials	Licensed Fludarabine 25mg/ml solution for injection or powder for reconstitution for injection Licensed Water for Injections Licensed Sodium Chloride Injection 0.9% w/v CE marked sterile syringes and syringe caps/hubs
	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):- . FLUDarabine xxxmg in 10ml Sodium Chloride 0.9% w/v For Intravenous Injection 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).