NHS England

Product specification: Nivolumab 50ml & 100ml infusion bags

	Name of product	Nivolumab infusion. Aseptically prepared from licensed sterile starting materials.
	Concentration	Concentration range 1mg/ml to 10mg/ml in infusion bags in accordance with the national dose banding tables. The Nivolumab 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	58mg to 110mg in 50ml (56ml to 61ml including rounded addition volume) 120mg to 440mg in 100ml (112ml to 125ml including addition volume) N.B. For doses below 58mg sufficient volume should be removed from a 50ml bag to achieve a final concentration of at least 1mg/ml
	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 Nivolumab 10mg/ml (Opdivo® or Biosimilar) concentrate solution for infusion. 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. NB: The brand name e.g. brand leader or subsequent biosimilars must be included on the label.
	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):- NIVOLumab (Brand Name) xxxmg 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 .
	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	The stability study should conform to the Standard Protocol for deriving and assessment of stability of Aseptic preparations (Biopharmaceuticals) published by the NHS Pharmaceutical QA Committee (3rd Edition, April 2017).