



ARCINOVA

Manufacturing Equipment List

Product Type	Equipment	Per Batch Scale (Max.)	Standard
STANDARD PRODUCTS			
Intravenous Solutions (Aseptically Prepared)	Manual Operation in a VHP sterilised Isolator (Grade A Environment in a Grade C room)	~200 units	GMP
Oral Solutions	ESCO EL20, L5T/AX5 Silverson Blenders, Heidolph Stirrers, Accuramatic and Peristaltic pumps	~20 litres	GMP
Oral Suspensions	ESCO EL20, L5T/AX5 Silverson Blenders, Heidolph Stirrers, Accuramatic and Peristaltic pumps	~20 litres	GMP
Oral Emulsions	ESCO EL20, L5T/AX5 Silverson Blenders, Heidolph Stirrers, Accuramatic and Peristaltic pumps	~20 litres	GMP
Formulated Capsule (Dry Blend)	Turbula Blender with manual or semi-automated filling	~0.5 kg	GMP
Formulated Capsule (Semi-Solid Matrix/Hard Gel Capsule)	Manual Operation (Conducted in an MSC)	~200 units	GMP
Comparator Products (Capsules)	Quantos Powder Dispensing System	~1000 units	GMP
API in a Capsule/Vial	2 x Quantos Powder Dispensing Systems	Batch sizes of <1000 to 5000 units (50-60 capsules/hour)	GMP
API in a Capsule	Capsugel Xcelodose® 600S Precision Powder Micro-Dosing System	Batch sizes of 5,000 to 30,000 units (200-400 capsules/hour)	GMP
API in a Capsule	3P R1000	Batch sizes of 10,000 to 50,000 units (600-800 capsules/hour)	GMP
Nano Suspensions	U.S. Stoneware Roller Mill; IKA Vertical Mill; Emulsiflex C5 high pressure homogenisers	~1000 ml	GMP
RADIOLABELLED PRODUCTS			
Radiolabelled Intravenous Solutions (Aseptically Prepared)	Manual Operation in a VHP sterilised Isolator (Grade A Environment in a Grade C room)	~200 units	GMP
Oral solutions	Manual Operation (Conducted in an MSC)	~200 units	GMP
Formulated Capsule (Semi-Solid Matrix)	Manual Operation (Conducted in an MSC)	~200 units	GMP
API in a Capsule	Manual Operation (Conducted in an MSC)	~1000 units	GMP
API in a Vial (Radiolabelled)	Manual Operation (Conducted in an MSC)	~200 units	GMP
Nano Suspensions	U.S. Stoneware Roller Mill; IKA Vertical Mill; Emulsiflex C5 high pressure homogenisers	~1000 ml	GMP



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CYTOTOXIC PRODUCTS			
Cytotoxic Intravenous Solutions (Aseptically Prepared)	Manual Operation in a VHP sterilised Isolator (Grade A Environment in a Grade C room)	~200 units	GMP
API in a Capsule	Manual Operation (Conducted in an Isolator)	~1000 units	GMP
API in a Vial (Cytotoxic)	Manual Operation (Conducted in an Isolator)	~200 units	GMP
Nano Suspensions	U.S. Stoneware Roller Mill and IKA Vertical Mill	~250 ml	GMP