

DATA SHEET

HLL BIOTECH LIMITED, CHENNAI

nne pharmaplan®	REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOOR		 HLL BIOTECH LIMITED <small>(Subsidiary of HLL Lifecare Limited) (A Government of India Enterprise)</small>
	Cryogenic storage container		
	Project No :	110831	
	Equipment ID :	Annexure 1	
	Document No :	DS-CSC 01	

1	Process requirements	
1.1	The Cryo storage container shall be used to cryopreserve cGMP cell banks for the purpose of manufacturing and testing vaccines as per pharmacopeia monograph (EP/USP).	
2	Technical Specifications	
2.1	Model	cGMP compliant portable model
2.2	System Capability	Minimum 350 - 400 vials
2.3	Storage Capacity	10 L/ (Near to standard) and to store 5.8 ml cryovials arranged in a secondary SS rack or cane holders.
2.4	Syorage Type	Manual loading of vials into the container
2.5	No.s of 2ml vials per canister/rack	Vendor to specify
2.6	Canister/Storage rack capacity	Vendor to specify
2.7	Static evaporation rate	Vendor to specify (with no product load)
2.8	Static Holding time	Minimum 120 days
2.9	Vessel exterior dimensions	Vendor to specify
2.10	Rack Dimension	Size should be suitable to store 350-400 vials of required capacity.
2.11	Quantity	2 nos of cryostorage container.
2.12	Operational Parameters	a.) Working pressure : 30 - 50 psi b.) Temperature : - 150 °C to - 190 °C
2.13	Additional Requirements	
2.14	Temperature	a) RTD sensors with an accuracy of +/- 1.0 degree C and a resolution of 0.1 degree C. b) Temperature displayin celsius and/or Fahrenheit . c) Hot gas bypass should be provided to vent warm nitrogen gas from the supply line before initiating LN2 fill d) The equipment should be able to store critical data with time for assessing the equipment performance and trouble shooting. e) Menu and settings with customizable security levels using password should be provided f) Temperature (at vapour phase and liquid phase) and liquid nitrogen level digital display g) Temperature and liquid nitrogen low level alarms
2.15	Storage requirements	a) Provision to ensure that cryovials are stored at vapour phase of nitrogen with physical separation from contact with liquid nitrogen. b) The cryo storage container should be designed to store and retrieve 5.8 ml cryovials arranged in a secondary SS container
2.16	Controls	a) Should have automatic liquid nitrogen level control with user defined parameters for low level alarm, low level fill point, high level fill point and high level alarm. The alarms should be in audio and visual modes. b) Liquid Nitrogen level measurement should have an accuracy of 15mm and a resolution of 5.0 mm c) The equipment should be able to store critical data with time for assessing the equipment performance and trouble shooting. d) Menu and settings with customizable security levels using password should be provided. e) De-fog system should be present to ensure good visibility f) Automatic monitoring and display of LN2 level g) Control pannel shall be mounted on the top of the unit for convenient assess and easy operation h) Remote alarm system shall be provided.
2.18	Performance requirement	Must meet all applicable regulatory/pharmacopeial requirement of performance of equipment and its component to ensure accuracy and reproducibility in test results
2.19	Electrical requirement	Vendor to specify
3	Material of Construction	
3.1	The MOC should be cGMP compliance	

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4 Specific requirements

4.1	LED display should display the level of Liquid Nitrogen and also the high and low level set points.
4.2	Should have easy access to the stored vials.
4.3	Should have full width top opening, compatible/suitable for storing and retrieving secondary SS holders containing the cryo-vials
4.4	"Castor wheels"- should be made of heavy duty cGMP compliant material, antistatic with lockable arrangement.
4.5	Should be suitable to be comfortably transported, placed and operated in the specified area
4.7	The wiring and LN2 transfer lines should be completely enclosed.

5 Other requirements

5.1	Vendor should provide all critical spares and accessories such as (i.e not limited to) SS square shaped canister racks, storage inventory system such as SS cryo boxes for 5.8 ml cryovials, LN2 transfer hose, cryoprotective gloves and safety goggles which should be provided with each equipment.
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6 Regulatory aspects

6.1	21 CFR Part 11 compliance
6.2	CE certification

7 Safety requirements

Following facilities must be provided to protect personnel and equipment:	
7.1	Appropriate closure of all parts of an instrument is essential.
7.2	Proper earthing is necessary for the instrument.
7.3	On power failure equipment should come in failsafe condition.
7.4	Should comply with safety requirements for pressure vessels and with EC Medical Devices Directive 93/42/EC
7.5	Container opening should be lockable to prevent unauthorized usage

8 Documents

Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file	
8.1	IOQ Protocol.
8.2	Operation and maintenance manuals shall be provided along with IQ and OQ documents during installation at site
8.3	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
8.4	All equipment warranty should be valid for one year from the date of completion.
8.5	Vendor should provide list of standard spare parts with ordering information.
8.6	Vendor should provide list of change parts (if applicable) with ordering information

9 Timelines

Not Applicable

NOTE: Accurate size and technical specification need to be mentioned by the vendor

AFI Approved for Enquiry			AFO Approved for Ordering			
00	2015-10-21	MNS	PULM	<input type="checkbox"/>	<input type="checkbox"/>	
Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1/2