

DATA SHEET

HLL BIOTECH LIMITED, CHENNAI

nne pharmaplan®	REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOOR		 <p style="font-size: small;">HLL BIOTECH LIMITED (Subsidiary of HLL Lifecare Limited) (A Government of India Enterprise)</p>
	Refrigerated Centrifuge		
	Project No :	110831	
	Equipment ID :	Annexure 1	
	Document No :	DS-FRC 01	

1	Process requirements	
1.1	The floor mounted refrigerated centrifuge shall be used for the separation process of various samples like, blood samples, tissue cultures and other samples in nalgene bottles/test tubes as per pharmacopeia monograph (EP/USP).	
2	Technical Specifications	
2.1	Model	cGLP model
2.2	Type	Floor Mounted with lockable castor wheels
2.3	Max. load(kg)	Vendor to specify
2.4	Max. density	Vendor to specify
2.5	Rotor type	Fixed angle and Swing bucket Rotor
2.6	Motor type	High-performance induction
2.7	Display type	Digital
2.8	Max. Force [xG]	7340 × g
2.9	Accuracy	± 10 RPM (display)
2.10	Time set/display	1 minute upto 100 minutes
2.11	Temperature range	(- 10) °C to 40 °C
2.12	Temperature control	± 2 °C
2.13	Control system	Microprocessor based
2.14	Dimensions (HxWxD) mm	Vendor to specify
2.15	Weight (kgs)	Vendor to specify
2.16	Expected operational hours per day	24 hrs
2.17	Quantity	8 No.s (Equipment ID:Ref.Table No:1)
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 of the outer body should be corrosion resistant, made up of cat metal ergonomic body with stain resistant enamel finish.	
3.2	Rotor MOC: Fiberlite carbon.	
4	Specific requirements	
4.1	Should be GLP Compliant	
4.2	Seamless, splash proof key pad with characteristic symbols should be provided for easy operation.	
4.3	Audible and optical alarms to indicate the end of operation and to indicate other abnormality conditions	
4.4	Rotor imbalance alarm should be given.	
4.5	Warning measures for high and low temperature control.	
4.6	Hinged type top cover should be provided , that can be operated using single hand.	

DATA SHEET

HLL BIOTECH LIMITED, CHENNAI

	REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOR		
	Refrigerated Centrifuge		
	Project No :	110831	
	Equipment ID :	Annexure 1	
	Document No :	DS-FRC 01	

4.7	Electronic monitoring, to display the cause in case of any fault
4.8	It should have over speed protection.
4.9	It should accept both conical and round bottom tubes.
4.10	The cleaning shall be able to be done manually
4.11	On power failure the instrument should run under alternate power supply without interruption of the operation.
4.12	Cooling mechanism should be provided to maintain the uniform temperature through out the operation.
5	Other requirements
5.1	The rotor should be easily removable using minimum tools.
5.2	A training for chemists has to be included in the offer.
5.3	It should be provided with automatic lid-lock system.
5.4	It should be provided with armored guard ring, and security key switch.
5.5	The system should be provided with anti-static clean room lockable wheels.
5.6	12 Number of 1L bottles should be provided.
6	Regulatory aspects
6.1	CE (Conformity European), UL (Underwriters laboratory), cUL (Canadian Underwriters Laboratory) compliance certificates
6.2	NPL (National Physical Laboratory) traceable Calibration certificates and calibration procedures.
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.
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

DATA SHEET

HLL BIOTECH LIMITED, CHENNAI

	REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOOR		 <small>HLL BIOTECH LIMITED (Subsidiary of HLL Lifecare Limited) (A Government of India Enterprise)</small>			
	Refrigerated Centrifuge					
	Project No :	110831				
	Equipment ID :	Annexure 1				
	Document No :	DS-FRC 01				
	AFI Approved for Enquiry			AFO Approved for Ordering		
01	2015-10-01	MNS	PULM	<input type="checkbox"/>	<input type="checkbox"/>	
Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1/2

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>
	Refrigerated Centrifuge		
	PROJECT NO :	110831	
	EQUIPMENT ID :		
	DOCUMENT NO :	DS-FRC 01	

TABLE NO: 1

Equipment ID	Block Name	Quantity No's	Room Name	Capacity	Speed range RPM	Room No	Room dimension in mm	Room height in mm
B1-RCFG 01,02	Diphtheria	2	Toxoid Concentration	6 no's of bottles, each bottle should hold 2000 mL	6000 - 8000	B1G060	4800 x 6510	3000
B2-RCFG 01,02	Tetanus	2	Concentration+Precipitation+Purification	7 no's of bottles, each bottle should hold 2000 mL	6000 - 8000	B2G039	7400 x 7230	3000
F2-RCFG 01, 02,03,04	Formulation	4	Gel preparation	6 no's of bottles, each bottle should hold 1000 mL	6000 - 8000	F1G038	5400 x 5850	3000

	AFI Approved for Enquiry		AFO Approved for Ordering			Sheet 2/2
00	09-09-2015	MNS	PULM	<input type="checkbox"/>	<input type="checkbox"/>	
Rev	Date	Completed By	Checked by	AFI	AFO	