

## DATA SHEET

### HLL BIOTECH LIMITED, CHENNAI

	<b>REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOOR</b>		 <small>HLL BIOTECH LIMITED (Subsidiary of HLL Lifecare Limited) (A Government of India Enterprise)</small>
	<b>Table top centrifuge</b>		
	<b>Project No :</b>	<b>110831</b>	
	<b>Equipment ID :</b>	<b>Annexure 1</b>	
	<b>Document No :</b>	<b>DS-CFG 01</b>	

<b>1</b>	<b>Process requirements</b>
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1.1	The table top centrifuge shall be used for the separation process of various samples like, blood samples, tissue cultures and other samples in conical flasks and test tubes as per pharmacopeia monograph (EP/USP).
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<b>2</b>	<b>Technical Specifications</b>
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2.1	Model	Basic cGLP model
2.2	Type	Table top
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	Brushless motor
2.7	Display type	Digital
2.8	Max. Force [xG]	20913 x g
2.9	Capacity	16 x15 mL
2.10	Quantity	5 No.s
2.11	Speed range	6000 - 8000 RPM
2.12	Step	10 RPM
2.13	Accuracy	± 10 RPM (display)
2.14	Time set/display	1 minute upto 100 minutes
2.15	Temperature	Ambient operation
2.16	Control system	Microprocessor based
2.17	Dimensions (HxWxD) mm	Vendor to specify
2.18	Weight (kgs)	Vendor to specify
2.19	Expected operational hours per day	24 hrs
2.20	Working temperature range	Approx 5 °C above ambient temperature to 95 °C
2.21	Performance requirement	Must meet all applicable regulatory/pharmacopeial requirement of performance of equipment and its component to ensure accuracy and reproducibility in test results
2.22	Electrical requirement	Vendor to specify

<b>3</b>	<b>Material of Construction</b>
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3.1	The MOC of the outer body should be corrosion resistant, made up of cat metal ergonomic body with stain resistant enamel finish.
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3.2	Rotor MOC: Fiberlite carbon.
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**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.
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 accepts 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.

**5 Other requirements**

5.1	The equipment must be portable.
5.2	The rotor should be easily removable using minimum tools.
5.3	A training for chemists has to be included in the offer.
5.4	There should be provision for electronic lid-lock system.

**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**

	<b>Following facilities must be provided to protect personnel and equipment:</b>
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**

	<b>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</b>
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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

<b>9</b>	<b>Timelines</b>
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	Not Applicable
	<b>NOTE:</b> Accurate size and technical specification need to be mentioned by the vendor

		AFI Approved for Enquiry		AFO Approved for Ordering		
01	2015-10-01	MGGP	PULM	<input type="checkbox"/>	<input type="checkbox"/>	
Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1/2

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**REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOOR**

**Table top centrifuge**

**PROJECT NO : 110831**

**EQUIPMENT ID :**

**DOCUMENT NO : DS-CFG-01**



**TABLE NO: 1**

Equipment ID	Block Name	Quantity	Room Name	Capacity	Speed range RPM	Room No	Room dimension in mm	Room height in mm
B1-CFG-01	Diphtheria	1	IPQC	16 x15 mL	6000 - 8000	B1G057	2200 x 3310	3000
B1-CFG-02	Pertussis	1	IPQC	16 x15 mL	6000 - 8000	B1G018	2200 x 3310	3000
B2-CFG-01	Tetanus	1	IPQC	16 x15 mL	6000 - 8000	B2G026	3200 x 5335	3000
M1-CFG-01	Sterility Media Preparation and Microbiology	1	Lab	16 x15 mL	6000 - 8000	M1G039	2920 x 2810	3000
A1-CFG-01	Animal Breeding	1	Animal health monitor	16 x15 mL	6000 - 8000	A1F012	3040 x 6350	3000

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