

DATA SHEET

HLL BIOTECH LIMITED, CHENNAI

REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII,
COONOR

Peristaltic Pump

Project No : 110831

Equipment ID : Annexure 1

Document No : DS-PSP-01

HLL BIOTECH LIMITED
(Subsidiary of HLL Micros Limited)
(A Government of India Enterprise)

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1 Process requirements

- 1.1 The peristaltic pump will be used with sterile tubing for aseptic transfer of various process fluids such as buffers and media in a cGMP clean room facility.

2 Technical Specifications

2.1	Model	cGMP compliant
2.2	Type	Portable type, with variable speed
2.3	Flow rate range	10 ml/ min - 18000 ml/ min
2.4	Display (RPM)	3 Digit, LED
2.5	Speed regulation (accuracy)	± 0.25 %
2.6	Dimension (L x W x H) in mm	to be confirmed by vendor
2.7	Suction axis	Horizontal
2.8	Tube sizes (Internal/External)	TBD
2.9	Operating temperature	5 °C-40 °C
2.10	Relative humidity	10-90 %
2.11	Displacement	Positive
2.12	Rotor Speed	0.1 - 400 rpm
2.13	Pump head	Single, should be compatible with silicon tubing of sizes 3.2 mm to 9.6 mm
2.14	Operation	Continuous
2.15	Pressure Range	20-40 psi
2.16	IP rating	IP 55/ IP 66
2.17	Motor direction	Clockwise and counter clock wise
2.18	Shipping Weight	Vendor to specify
2.19	Electricity Consumption	Vendor to specify

3 Material of Construction


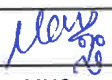

3.1	Main body	SS
3.2	Rollers, Pump case, Shaft, Bracket	SS
3.3	Tube	Platinum cured silicon tubing USP Class VI compliant

4 Specific requirements

- 4.1 Peristaltic pump should include (not limited) pump, pump head and 3 meters each of required sizes of platinum cured silicone tubing
- 4.2 The supplied pump head should accept multiple tubing sizes and operate to deliver the required minimum and maximum volumes
- 4.3 Peristaltic pump is capable for continuous operation and pumping of process fluid along with metering the volume of fluid.
- 4.4 Microprocessor controlled with soft-touch keypad and with easy-to-read LCD Screen along with LED light display to show the mode of the pump.
- 4.5 Pump Drives should be based on digital variable speed.
- 4.6 Stepper motor drive for uniform rpm digital variable speed
- 4.7 Digital speed setting, reversible flow, programmable pump

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4.8	Pump speed should not vary with power fluctuations (Near pulseless flow)					
5	Other requirements					
5.1	Should be certified as water tight					
5.2	The equipment must be easy to clean, all external surface of the equipment and pump head should be easily disinfectable with standard disinfectant such as 70 % IPA.					
5.3	All bolts, nuts on the exterior part of equipment should be with cap head or cap nut.					
5.4	Manual/ analog/ digital RS 232 control required					
6	Regulatory aspects					
6.1	NA					
7	Safety requirements					
7.1	Pump head should be covered with the safety enclosure					
7.2	In event of equipment malfunction or loss of utilities, the unit must contain all necessary protection devices that the equipment and the product remain in a safe condition.					
7.3	Noise level should be less than 75 decibel at 1 meter distance.					
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					
	AFI Approved for Enquiry			AFO Approved for Ordering		
						
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Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1/2

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REVIVAL OF DPT VACCINE
MANUFACTURING FACILITY, PII, COONOOR

Peristaltic Pump

Project No : 110831

EQUIPMENT ID :

Document No: DS-PSP-01

HLL BIOTECH LIMITED
(Subsidiary of HLL Lifescare Limited)
(A Government of India Enterprise)

TABLE NO: +A8:G33 1

Equipment ID	Block Name	Quantity (no's)	Room Name	Room No	Room dimension in mm	Room height in mm
B1-PSP 01	Diphtheria	1	Fermentation	B1G048	5800×6510 4300×4610 1600×4610	4000
B1-PSP 02	Diphtheria	1	Media and Buffer Room	B1G069	4900×3610 2000×2900	4000
B1-PSP 03	Diphtheria	1	Toxoid Concentration	B1G060	4800×6510	3000
B2-PSP 01	Tetanus	1	Fermentation	B2G027	9500×6300 7400×3800 2000×3800	4000
B2-PSP 02	Tetanus	1	Media and Buffer preparation	B2G033	5100×3680	4000
B2-PSP 03	Tetanus	1	Concentration+Precipitation+Purification	B2G039	7400×7230	3000
F1-PSP-01	Formulation	2	Gel preparation	F1G038	5400×5850	3000

AFI Approved for Enquiry

AFO Approved for Ordering

Sheet 2/2

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