

Equipment Specification Data Sheet

Equipment Name: Peristaltic pump

Document No.: DS-PSP 01


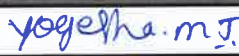

Revision: 03

Project No.: 120310

Project Name: Integrated Vaccines Complex,
 Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
F2	Bacterial formulation	F2 PSP 01	1000 ml/min to 10000ml/min	1
F2	Bacterial formulation	F2 PSP 02	100 ml/min to 3000ml/min	1
F2	Bacterial formulation	F2 PSP 03, 04	100 ml/min to 3000ml/min	2
B4	Rabies Bulk	B4 PSP 01, 02	10 ml/min to 3000ml/min	2
B4	Rabies Bulk	B4 PSP 03, 04	10 ml/min to 3000ml/min,	2
B4	Rabies Bulk	B4 PSP 05	10 ml/min to 18000ml/min	1
Q1	Admin, QA and QC	Q1 PSP 01	100 ml/min to 3000ml/min	1
F1	Viral Formulation	F1-PSP-01	10 ml/min to 3000 ml/min	1

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
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Project Name: Integrated Vaccines Complex,
Chengalpattu


HLL Biotech Limited

Name	Designation	Signature	Date
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HLL Biotech Limited, Chennai				
nne pharmaplan®		INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 <small>HLLBIOTECH LIMITED (Subsidiary of HLL Lifescare Limited) (A Government of India Enterprise)</small>
		Equipment Name	Peristaltic Pump	
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		Revision No.	03	
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 cell culture media in a cGMP clean room facility.			
2	Equipment ID	Flow rate	Quantity	
2.1	F2-PSP 01	1000 ml/min to 10000ml/min	1 no.	
2.2	F2-PSP 02	100 ml/min to 3000ml/min	1 no.	
2.3	F2-PSP 03, 04	100 ml/min to 3000ml/min	2 nos.	
2.4	B4 PSP 01, 02	10 ml/min to 3000ml/min	2 nos.	
2.5	B4 PSP 03, 04	10 ml/min to 3000ml/min,	2 nos.	
2.6	B4-PSP 05	10 ml/min to 18000ml/min	1 no.	
2.7	Q1-PSP 01	100 ml/min to 3000ml/min	1 no.	
2.8	F1-PSP-01	10 ml/min to 3000 ml/min	1 no.	
3	Technical Specification			
3.1	Model	cGMP compliant		
3.2	Type	Portable type, with variable speed		
3.3	Display (RPM)	LED		
3.4	Speed regulation (accuracy)	± 0.25 %		
3.5	Dimension (L x W x H) in mm	Vendor to specify		
3.6	Suction axis	Horizontal		
3.7	Tube sizes (Internal/External)	Vendor to specify as per flow rate requirements		
3.8	Operating temperature	5 °C–40 °C		
3.9	Relative humidity	10–90 %		
3.10	Displacement	Positive		
3.11	Rotor Speed	0.1 - 600 rpm		
3.12	Pump head	Single, should be compatible with silicon tubing of sizes 3.2 mm to 9.6 mm ID		

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HLL Biotech Limited Integrated Vaccines Complex, Chengalpattu	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
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3.13	Operation	Continuous and dosing
3.14	Pressure Range	20-40 psi
3.15	IP rating	IP 55/ IP 66
3.16	Motor direction	Clockwise and counter clock wise
3.17	Shipping Weight	Vendor to specify
3.18	Power Requirement	To be compatible to standard Indian Power supply Socket
4	Material of Construction	
4.1	Main body	SS
4.2	Rollers, Pump case, Shaft, Bracket	SS
4.3	Tube	Platinum cured silicon tubing USP Class VI compliant
5	Specific Equipment requirement	
5.1	Individual peristaltic pump package should include (not limited) pump, pump head and 3 meters each of required sizes of platinum cured silicone tubing.	
5.2	The supplied pump head should accept multiple tubing sizes and operate to deliver the required minimum and maximum volumes.	
5.3	Peristaltic pump for continuous operation and pumping of process fluid along with metering the volume of fluid.	
5.4	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.	
5.5	Digital variable speed based pump drives; Stepper motor drive for uniform rpm digital variable speed.	
5.6	Digital speed setting, reversible flow, programmable pump.	
5.7	Pump speed should not vary with power fluctuations.	
5.8	Autocalibration shall be provided for the equipment with ID.	
5.9	Equipment shall be compatible for cleaning with all standard disinfectants.	
6	Other requirement	
6.1	Should be certified as water tight.	

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6.2	Manual/ analog/ digital RS 232 / 485 control required	
6.3	Training/Demo for the users on operation and cleaning to be provided.	
7	Regulatory aspects	
7.1	CE certification	
8	Safety requirements	
	Following facilities must be provided to protect personnel and equipment:	
8.1	Pump head should be covered with the safety enclosure	
8.2	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.	
8.3	Noise level should be less than 85 decibel at 1 meter distance.	
8.4	Appropriate closure of all parts.	
8.5	Proper earthing is necessary.	
9	Documents	
	Following documents, but not limited to these, are expected from the vendor as part of the supply package in the hard copy as well as editable electronic file	
9.1	IOQ documents	
9.2	Operation and maintenance manual should be provided along with IOQ documents during installation at site.	
9.3	Warranty letter for 1 year from the date of supply.	
9.4	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.	
10	Timelines	
10.1	Not applicable	
11	Preferred list of Makes	
11.1	Watson Marlow, Master Flex, ISMA tec, Lambda	
	NOTE: Accurate size and technical specification need to be mentioned by the vendor	

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Table-1: Equipment location					
Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
F2-PSP 01	Bacterial formulation	Disinfectant preparation	F2G024	2380 x 4910	3000
F2-PSP 02	Bacterial formulation	Blending	F2G028	6090 x 8940	4000
F2-PSP 03, 04	Bacterial formulation	Buffer & solution Preparation	F2G030	5200 x 6890	3500
B4 PSP 01, 02	Rabies Bulk	Cell Culture	B4G036	6000 X 5000	2700
B4 PSP 03, 04	Rabies Bulk	Virus Propagation	B4G046	9218 X 5801	2700
B4-PSP 05	Rabies Bulk	Purification	B4G057	9126 X 5750	3000
Q1-PSP 01	Admin, QA and QC	Media preparation & sterilisation	Q1S051	5260 X 3550	2400
F1-PSP-01	Viral Formulation	Blending and Formulation Room	F1G080	5420 X 6260	4000
Table-2: Change Log					
Date	Name	Revision	Section	Change/Comment	
11-07-2014	Niharika Ruhela	00	-	New document	
9-09-2014	Niharika Ruhela	01	All	Updated as per comments received from HBL dated 13-05-2014	
07-01-2015	Yogesha M J	02	All	Updated as per comments given by HBL team during meeting dated 07-01-2015 at HBL office	
06-05-2015	Niharika Ruhela	03	All	Updated as per comments from client dated 27-02-2015	
Table-3: Annexure					
Not applicable					