

Equipment Specification Data Sheet

Equipment Name: Flocculation Water Bath

Document No.: DS-FWB 02

Revision: 01

Project No.: 120310

Project Name: Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
Q1	Admin,QA and QC	Q1-FWB 01	6-8 L	1

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
Prepared by			
Mr. Sandeep Kumar	Process Engineer	<i>Sandeep</i>	26.02.2016
Checked by			
Mr. Sridhar Babu	Senior Engineer - Process	<i>K. Sridhar Babu</i>	26.02.2016
Approved by			
Dr. Harshad Mali	Lead Engineer - Process	<i>H.M.</i>	26.02.2016

HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
User department: Animal House	<i>na</i>	<i>[Signature]</i>	
User department: Quality Control <i>SANJEEV KUMAR R</i>	<i>Manager</i>	<i>SK</i>	01.03.2016
Project / Engineering Department <i>VIGNESHWARAN</i>	<i>DM. PROECS</i>	<i>[Signature]</i>	29.02.16
Approved by			
Head of the department Animal House	<i>na</i>	<i>[Signature]</i>	
Head of the department Quality Control <i>V. SIVAKANESH</i>	<i>Manager</i>	<i>[Signature]</i>	01.03.16
Head of the department <i>S. Sridhar Babu</i>	<i>DM</i>	<i>[Signature]</i>	01.03.16
Authorized by			
Project Authority <i>RAMAN K. R.</i>	<i>CEO</i>	<i>[Signature]</i>	7.3.16

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HLL Biotech Limited, Chennai			
nne pharmaplan*	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 <small>HLL BIOTECH LIMITED A Division of HLL Special Limited A Government of India Enterprise</small>
	Equipment Name	Flocculation Water bath	
	Document No.	DS-FWB 02	
	Revision No.	01	
1	Process requirements		
1.1	The Water bath is used for the incubation of various samples under controlled temperature.		
2	Equipment ID		
2.1	Q1-FWB 01		
3	Technical Specification		
3.1	Model	Circulating	
3.2	Heating capacity(kW)	Vendor to specify	
3.3	Inner chamber size(LxWx H)	width minimum 12cm, length minimum 31cm	
3.4	External dimension(LxWx H)	Vendor to specify	
3.5	Temperature controlling mechanism	Microprocessor based PID temperature controller	
3.6	Expected operational hours per day	24 hrs	
3.7	Display	LCD/LED display for temperature	
3.8	Working temperature range	Ambient temperature + 10 ⁰ C to 60 ⁰ C	
3.9	Temperature stability	± 0.2 ⁰ C	
3.10	Resolution	±0.1 ⁰ C	
3.11	Temperature selection	Digital Microprocessor controller (soft touch)	
3.12	Quantity	1 no.	
3.13	Power Requirement	To be compatible to standard Indian Power Supply.	
3.14	Pump Capacity	Vendor to specify	
4	Material of Construction		
4.1	Bath tank	High quality acrylic/Polycarbonate/cGMP complaint transparent material	
4.2	Heating element	Vendor to specify	
4.3	Racks for test tubes	Shall provide for SS racks for accomodating 13mm diameter tubes	
5	Specific Equipment Requirements		
5.1	Should be cGMP Compliant		
5.2	Seamless,splash proof key pad with characteristic symbols should be provided for easy operation.		
5.3	Audible and optical alarms are required for protecting from dry-running condition.		
5.4	Warning measures (audio visual alarm) for deviation of temperature.		

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5.5	The water bath shall not have any sharp corners/edges.		
5.6	Equipment shall be compatible for cleaning with all standard disinfectants.		
6	Other requirement		
6.1	The equipment must be portable.		
6.2	Training/Demo for the users on operating 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	Appropriate closure of all parts.		
8.2	Proper earthing is required		
8.3	Water bath should be insulated to avoid dissipation of heat to external surface		
9	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		
9.1	IOQ documents.		
9.2	Operation and maintenance manuals shall 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.		
9.5	List of standard spare parts with ordering information.		
10	Timelines		
10.1	NA		
11	Preferred list of Makes		
11.1	JEIOTEK, JULABO, VELP		
	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
Q1-FWB 01	QC	Chemical lab/ Bio chemistry	Q1S022	6250 X 7350	2400
Table-2: Change Log					
Date	Name	Revision	Section	Change/Comment	
18-02-2016	Sandeep Kumar	00	-	New Document	
24-02-2016	Sandeep Kumar	01	-	Updated as per comments received from HBL on 22-02-2016	