

Equipment Specification Data Sheet

Equipment Name: Water bath

Document No.: DS-WBH 02

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines
 Complex, Chengalpattu


Block Code	Block Name	Identification No.	Capacity	Quantity
B4	Rabies Bulk	B4-WBH 01	To accommodate 2 no.s of 10 L glass bottles (diameter 24cm)	1
G1	Animal House	G1-WBH 01	5 to 15	1
Q1	Admin QA & QC	Q1-WBH 01	15 to 20	1
Q1	Admin QA & QC	Q1-WBH 02	15 to 20	1
Q1	Admin QA & QC	Q1-WBH 03	15 to 20	1
Q1	Admin QA & QC	Q1-WBH 04	15 to 20	1


NNE Pharmaplan India Limited


Name	Designation	Signature	Date
Prepared by			
Mr. Sandeep Kumar	Process Engineer	<i>Sandeep</i>	18/02/16
Checked by			
Mr. Yogesha M J	Process Engineer	<i>Yogesha M J</i>	18/02/2016
Approved by			
Dr. Harshad Mali	Lead Engineer - Process	<i>Harshad</i>	19/02/16


HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
User department: Rabies Bulk <i>P. MOVIN KUMAR</i>	Deputy Manager	<i>P. Mo Vin</i>	03.03.16
User department: Animal House <i>K. RAJENDRAN</i>	Deputy Manager	<i>K. Rajendran</i>	02.03.16
User department: Quality Control <i>SENSEER KUMAR</i>	Manager	<i>Senseer</i>	29/02/16
Project / Engineering department <i>A. ANTO FELIX</i>	Manager	<i>A. Antofelix</i>	29.02.16
Approved by			
Head of the department Rabies Bulk <i>Dr. P. MOVIN KUMAR</i>	Project head (U)	<i>Dr. P. Mo Vin</i>	03.03.2016
Head of the department Animal House <i>Dr. K. RAJENDRAN</i>	MANAGER	<i>K. Rajendran</i>	03.03.16
Head of the department Quality Control <i>V. RAJAGAN</i>	Manager	<i>V. Rajagan</i>	3.03.16
Head of the department <i>Dr. SURESH K. R.</i>	DM	<i>Dr. Suresh K. R.</i>	04.03.16
Authorized by			
<i>Ramank R.</i>	C.E.O.	<i>Ramank</i>	7.3.16

Equipment Specification Data Sheet					
HLL Biotech Limited, Chennai					
HLL Biotech Limited INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 <small>HLL BIOTECH LIMITED (A Subsidiary of HLL Lifesciences Limited) (A Government of India Enterprise)</small>			
				Equipment Name	Water bath
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1 Process Requirements					
1.1	The Water bath shall be used for the incubation of various samples under controlled temperature				
2	Equipment ID	Capacity (L)	Type		
2.1	B4-WBH 01	To accommodate 2 no.s of 10 L glass bottles (diameter 24cm)	Stationary		
2.2	G1-WBH 01	5 to 15	Stationary		
2.3	Q1-WBH 01	15 to 20	Stationary		
2.4	Q1-WBH 02	15 to 20	Circulating/Multiside Heating		
2.5	Q1-WBH 03	15 to 20	Circulating/Multiside Heating		
2.6	Q1-WBH 04	15 to 20	Stationary		
3 Technical Specifications					
3.1	Model	cGMP model			
3.2	Heating capacity(kW)	Vendor to specify			
3.3	Inner chamber size (LxWxH)	Vendor to specify			
3.4	External dimension(LxWxH)	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	LED display for temperature			
3.8	Working temperature range	Ambient temperature +10°C to 95°C			
3.9	Temperature stability	±0.2 °C			

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3.10	Temperature Uniformity	±0.1 °C		
3.11	Resolution	±0.1 °C		
3.12	Temperature selection	Digital Microprocessor controller (soft touch)		
3.13	Quantity	6 No's		
3.14	Power requirement	To be compatible to standard Indian Power supply socket		
4 Material of Construction				
4.1	Inner chamber	SS 304 mirror finish		
4.2	Exterior chamber	cGMP compliant exterior		
4.3	Heating element	Vendor to specify		
4.4	Lid or top cover	cGMP compliant material preferably transparent		
4.5	Perforated tray	Stainless Steel		
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 to ± 0.5 °C from set point			
5.5	Drain should be provided for the ease of emptying the bath.			
5.6	All parts in contact with water should be made of SS304			
5.7	Minimum and Maximum Fill level should be clearly indicated by a marking on the inner surface of the bath.			
5.8	The lid should be designed in such a way that the dropping back of the condensate into the test tubes/containers should be avoided.			
5.9	The water bath outer surface should not have any sharp corners.			
5.10	The equipment shall be compatible for cleaning with all standard disinfectants.			
6 Other Requirements				
6.1	The equipment must be portable			
6.2	Training/Demo for the users on operation and cleaning be provided.			
7 Regulatory Aspects				
7.1	CE certificate.			

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HLL pharma plan	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 HBL HLL BIOTECH LIMITED <small>(Subsidiary of HLL (Karnataka Limited) (a Government of India Enterprise)</small>
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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 necessary.		
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 the 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	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	
B4-WBH 01	Rabies Bulk	Cell Lab - 1	B4G038	5900 x 4850	2700	
G1-WBH 01	Animal House	Lab area - Testing	G1G055	4700 x 7300	2700	
Q1-WBH 01	Admin QA & QC	Chemical Lab / Bio Chemistry	Q1S022	6240 x 6805	2400	
Q1-WBH 02-03	Admin QA & QC	Chemical Lab / Bio Chemistry	Q1S022	6240 x 6805	2400	
Q1-WBH 04	Admin QA & QC	Media preparation and sterilization	Q1S051	5160 x 3510	2400	
Table-2: Change Log						
Date	Name	Revision	Section	Change/Comment		
10-02-2016	Sandeep Kumar	00	-	New document		
Table-3: Annexure						
Not applicable						