

Equipment Specification Data Sheet

Equipment Name: Water bath

Document No.: DS-WBH 01

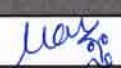
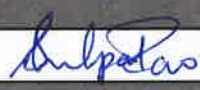
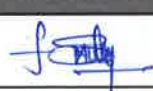
Revision: 04

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. Manohar M S	Engineer - Process		6/7/2015
Checked by			
Ms. Shilpa Rao	Senior Engineer - Process		6/7/2015
Approved by			
Mr. Vikas Katial	GM - Projects (SME) & Head COC Vaccines		6/7/2015

Equipment Specification Data Sheet








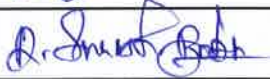

Equipment Name: Water bath


Document No.: DS-WBH 01


Revision: 04


Project No.: 120310


Project Name: Integrated Vaccines
 Complex, Chengalpattu

HLL Biotech Limited			
Name	Designation	Signature	Date
Reviewed by			
Navin Kumar. P	Deputy Manager		9/7/2015
Yashwanth Reddy	Deputy Manager		9/7/2015
Sangeet Kumar. R	Manager		8/7/2015
Polina Sreenath	Deputy Manager		8/7/2015
Approved by			
Dr. Juliet Selvi	Head - Viral Vaccine		9/7/2015
Dr. K. A. Anil Anand	Manager		9/7/2015
Sita Chenech. V	Manager		10/7/2015
Suresh Babu. R	DUM		10/7/2015
Authorized by			
Ramas. K. Ramachandran	CEO		13/7/2015

Equipment Specification Data Sheet				
HLL Biotech Limited, Chennai				
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU			 <small>HLL BIOTECH LIMITED Subsidiary of HLL Lifesciences Limited a Government of India Enterprise</small>
	Equipment Name	Water bath		
	Document No.	DS-WBH 01		
	Revision No.	04		
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	Pump capacity flow rate (Liter per minute)
2.1	B4-WBH 01	To accommodate 2 no.s of 10 L glass bottles (diameter 24cm)	Stationary	NA
2.2	G1-WBH 01	5 to 15	Stationary	NA
2.3	Q1-WBH 01	15 to 20	Stationary	NA
2.4	Q1-WBH 02	15 to 20	Circulating	10 to 15
2.5	Q1-WBH 03	15 to 20	Circulating	10 to 15
2.6	Q1-WBH 04	15 to 20	Stationary	NA
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 +5°C to 100°C		
3.9	Temperature stability	±0.2 °C		
3.10	Temperature Uniformity	±0.1 °C		

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	Water bath
	Document No.	DS-WBH 01
	Revision No.	04
		
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	Stainless Steel
4.4	Lid or top cover	cGMP compliant material preferably transparent
4.5	Perforated tray	Stainless Steel
4.6	Racks for test tubes	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.	

Equipment Specification Data Sheet				
HLL Biotech Limited, Chennai				
nne pharmaplan®		INTEGRATED VACCINES COMPLEX, CHENGALPATTU		
		Equipment Name	Water bath	
		Document No.	DS-WBH 01	
		Revision No.	04	
7	Regulatory Aspects			
7.1	CE certificate.			
8	Safety Requirements			
	Following 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			

Equipment Specification Data Sheet					
HLL Biotech Limited, Chennai					
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU			 <small>HLL BIOTECH LIMITED Subsidiary of HLL Life Sciences Limited a Government of India Enterprise</small>	
	Equipment Name	Water bath			
	Document No.	DS-WBH 01			
	Revision No.	04			
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	
11-07-2014	Manohar	00		New document	
04-08-2014	Manohar	01	All	Updated as per comments received from HBL dated 04-08-2014	
27-10-2014	Manohar	02	All	Updated as per comments received from HBL dated 15-10-2014	
07-01-2015	Yogesha M J	03	All	Updated as per comments given by HBL team during meeting dated 07-01-2015 at HBL office	
06-05-2015	Manohar	04	All	Updated as per comments received from HBL dated 27-02-2015	
Table-3: Annexure					
Not applicable					

Equipment Specification Data Sheet

Equipment Name: Flocculation Water Bath

Document No.: DS-FWB 01

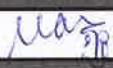
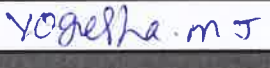

Revision: 03

Project No.: 120310




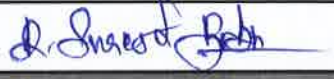
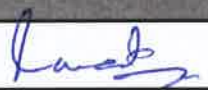
Project Name: Integrated Vaccines Complex,
Chengalpattu

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


NNE Pharmaplan India Limited


Name	Designation	Signature	Date
Prepared by			
Mr. Manohar M S	Engineer - Process		8/6/15
Checked by			
Mr. Yogesha M J	Engineer - Process		8/6/15
Approved by			
Mr. Vikas Katial	GM - Projects (SME) & Head COC Vaccines		9/6/15

HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
Sanjeev Kumar. R	Manager		12/6/15
Polima Sreenath	Deputy Manager		12/6/15
Approved by			
V. Sivaganesk	Manager		19/6/15
D. Suresh Babu	DM		22/6/15
Authorized by			
Raman. K. Ramachandran	CEO		24/6/15

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
HLL Biotech Limited Chennai	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	Flocculation Water bath
	Document No.	DS-FWB 01
	Revision No.	03
HLL BIOTECH LIMITED (Subsidiary of HLL Biotech Limited) (A Government of India Enterprise)		
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 + 5 °C to 60 °C
3.9	Temperature stability	± 0.2 °C
3.10	Resolution	±0.1 °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(Liter per minute)	Vendor to specify
4	Material of Construction	
4.1	Bath tank	High quality acrylic/Polycarbonate/cGMP complaint transparent material
4.2	Heating element	Stainless Steel
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.	

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne pharma plan	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 HLL BIOTECH LIMITED (Subsidiary of HLL Pharma Limited) (A Company of India Biotech)
	Equipment Name	Flocculation Water bath	
	Document No.	DS-FWB 01	
	Revision No.	03	
5.4	Warning measures (audio visual alarm) for deviation of temperature.		
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		

Equipment Specification Data Sheet					
HLL Biotech Limited, Chennai					
nne pharmaplan	INTEGRATED VACCINES COMPLEX, CHENGALPATTU			 HBL HLL BIOTECH LIMITED <small>(a subsidiary of HLL Biotech Limited) (a Government of India Enterprise)</small>	
	Equipment Name	Flocculation Water bath			
	Document No.	DS-FWB 01			
	Revision No.	03			
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	
07-07-2014	Manohar M S	00	-	New Document	
16-10-2014	Manohar M S	01	All	Updated as per comments received from HBL dated 15-10-2014	
09-01-2015	Manohar M S	02	All	Updated as per comments given by HBL team during meeting dated 06-01-2015 at HBL office	
06-05-2015	Manohar M S	03	All	Updated as per comments received from HBL dated 27-02-2015	
Table-3: Annexure					
Not applicable					