

Equipment Specification Data Sheet

Equipment Name: Ultrasonic
Bath

Document No.: DS-USB 01


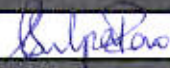

Revision: 03

Project No.: 120310

Project Name: Integrated Vaccines Complex,
Chengalpattu


Block Code	Block Name	Identification No.	Capacity	Quantity
Q1	Admin QA&QC	Q1-USB-01	10L or near to its standard	1


NNE Pharmaplan India Limited


Name	Designation	Signature	Date
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HLL Biotech Limited

Name	Designation	Signature	Date
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Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
HLL Biotech Limited Chennai	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	Ultrasonic Bath
	Document No.	DS-USB 01
	Revision No.	03
		
1	Process requirements	
1.1	Ultrasonic bath is used for filter cleaning and HPLC mobile phase degassing	
2	Equipment ID	
2.1	Q1-USB-01	
3	Technical Specification	
3.1	Model	Vendor to specify
3.2	Display	LCD/LED
3.3	Time Range	Vendor to specify
3.4	Temperature Range	Ambient to 65 °C
3.5	Bath Capacity	10L or near to its standard
3.6	Ultrasonic frequency	35 to 45 kHz
3.7	Degas/Autogas	Required
3.8	Drain Duct	Required
3.9	Power required	To be compatible with standard Indian power supply socket
4	Material of Construction	
4.1	Body	Vendor to specify
4.2	Inner Chamber	Stainless steel
5	Specific Equipment requirement	
5.1	Settable Operating temperature and Time.	
5.2	Equipment shall be compatible for cleaning with all standard disinfectants.	
6	Other requirement	
6.1	Wire Basket (MOC: Stainless steel) to be provided.	
6.2	Training/Demo for the users on operation and cleaning to be provided.	
7	Regulatory aspects	
7.1	The equipment shall be as per GLP standards.	
7.2	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 necessary.	
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	IQ Protocol.	
9.2	Operation and maintenance manuals shall be provided along with IQ documents during installation at site.	
9.3	Warranty 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 procedure.	

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nne pharmaplan	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 HLL BIOTECH LIMITED <small>(Subsidiary of HLL, A Government of India Enterprise)</small>
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10	Timelines		
10.1	NA		
11	Preferred list of Makes		
11.1	Grant, Elma Sonic P, Cole parmer		
NOTE: Accurate size and technical specification need to be mentioned by the vendor.			

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Equipment Name	INTEGRATED VACCINES COMPLEX, CHENGALPATTU			 HLL BIOTECH LIMITED <small>(A Subsidiary of HLL, a Public Limited Company) (A Government of India Enterprise)</small>	
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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-USB-01	Admin QA&QC	Instrumentation Lab	Q1S020	6400×3450	2400
Table-2: Change Log					
Date	Name	Revision	Section	Change/Comment	
11-03-2014	Kiran Kumar M S	00	-	New document.	
27-10-2014	Kiran Kumar M S	01	All	Updated as per comments received from HBL dated 10-10-2014.	
06-01-2015	Kiran Kumar M S	02	All	Updated as per comments given by HBL team during meeting dated 06-01-2015 at HBL office.	
29-04-2015	Kiran Kumar M S	03	All	Updated as per comments given by HBL team dated on 27-02-2015.	
Table-3: Annexure					
Not applicable					