

Equipment Specification Data Sheet

Equipment Name: Ultrasonic Bath

Document No.: DS-USB 02

Revision: 01

Project No.: 120310

Project Name: Integrated Vaccines Complex,
Chengalpattu


Block Code	Block Name	Identification No.	Capacity	Quantity
Q1	Admin, QA & QC	Q1-USB 01	10 L	1


NNE Pharmaplan India Limited


Name	Designation	Signature	Date
Prepared by			
Ms. Niharika Ruhela	Process Engineer		26-02-2016
Checked by			
Mr. Sridhar Babu	Senior Engineer - Process		26-02-2016
Approved by			
Dr. Harshad Mali	Lead Engineer - Process		26-02-2016

HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
User department: (QC) SANDHEE KUMAR P.	Manager		03.03.16
Project / Engineering department A. ANTO FELIX	Manager		29.02.16
QA department			
Approved by			
Head of the department (QC) K. Sivaganesh	Manager		04/03/16
Head of the department (QA) A. SURESH BABU	Manager		04.03.16
Authorized by			
Project Authority Raman K. R.	C-E-O		7.3.16

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HLL Biotech Limited, Chennai		
nne pharmaplan*	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	Ultrasonic Bath
	Document No.	DS-USB 02
	Revision No.	01
		
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 Certificate	
8	Safety requirements	
	Following facilities must be provided to protect personnel and equipment	
8.1	Appropriate closure of all parts.	

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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	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 instrument with respect to the traceable national reference standard instrument and their calibration procedure.	
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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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	-	-
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	
Table-3: Annexure					
Not applicable					