

Equipment Specification Data Sheet

Equipment Name: Water Testing Manifold

Document No.: DS-WTM 01

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex,
 Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
Q1	Admin, QA & QC	Q1-WTM 01- 02	-	2

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
Prepared by			
Mr. Sharique	Process Engineer	for Sandeep	11-02-2016
Checked by			
Mr. Yogesha M J	Process Engineer	Yogesha. m.j.	11-02-2016
Approved by			
Dr. Harshad Mali	Lead Engineer - Process	for Harshad Mali	11/02/2016

HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
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Project / Engineering department VIGNESHWARAN. J	DM-PROJECTS	Vigneshwaran	15/2/16
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Head of the department: QC Block VIGNESHWARAN. J	Manager	Vigneshwaran	15/02/2016
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Authorized by			
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Equipment Specification Data Sheet
HLL Biotech Limited, Chennai

nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 HBL <small>HLL BIOTECH LIMITED Subsidiary of HLL Biotech Limited # Government of India Enterprise</small>
	Equipment Name	Water Testing Manifold	
	Project #	120310	
	Document #	DS-WTM 01	
1	Process requirements		
1.1	This equipment is for holding the samples in the manifold used for microbiological testing (Water and Sterility)		
2	Equipment ID		
2.1	Q1-WTM 01-02		
3	Technical Specification		
3.1	Model	cGMP	
3.2	Type	Portable	
3.3	Quantity	02 nos	
3.4	No. of Channels	06 nos	
3.5	Construction	As per vendor specification	
3.6	Description	Non toxic, unbreakable polysulfone funnel	
3.7	Weight	<i>Vendor to specify</i>	
3.8	Dimension	<i>Vendor to specify</i>	
3.9	Funnel specification	Polycarbonate/related material autoclavable	
		Graduated 250 ml capacity with holder	
3.10	Funnel Required Qty	50 funnels	
3.11	Filter Diameter	47mm	
3.12	Maximum operating pressure	Vaccum only	
3.13	Sterilization	Should be sterilizable at 121°C	
4	Material of Construction		
4.1	Outer Body	SS (Manifold)/ PTFE (Funnel) autoclavable	
5	Specific Equipment requirement		
5.1	Fully comply national and international standards for environmental monitoring		
5.2	Low running cost & operational flexibility		
5.3	100% sampling efficiency		
5.4	The equipment shall be able to withstand the mechanical stresses.		
5.5	The equipment should be provided with handle to carry from one place to other place easily.		
6	Other requirement		
6.1	The equipment should be easy to use and clean.		
7	Regulatory guidelines / standards		
7.1	The equipment shall be as per cGLP standards.		
8	Safety requirements		
8.1	Vendor to specify		
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	Operation and maintenance manuals		
9.2	One year Warranty letter.		
9.3	List of standard spare parts with ordering information.		
9.4	Training for the technical persons to be included to handle the equipment.		

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HLL Biotech Limited, Chennai

nne pharmaplan	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 <small>HLL BIOTECH LIMITED (A Subsidiary of HLL Lifecare Limited of Government of India Enterprise)</small>
	Equipment Name	Water Testing Manifold	
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10	Timelines
	Not Applicable
11	List of Preferred Make
11.1	Merck, Sartorius & Cole Parmer
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

TABLE NO: 1

EQUIPMENT ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1-WTM 01-02	Admin, QA & QC	Water test lab	Q1S043	-	-

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
09-09-2015	Tushar	00	-	New document

Table-3: Annexure

Not applicable