

Equipment Specification Data Sheet

Equipment Name: Type I Ultra pure water system

Document No.: DS-MQW 01

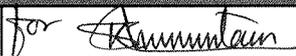
Revision: 00

Project No.: 120310

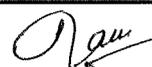
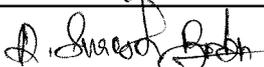
Project Name: Integrated Vaccines Complex, Chengalpattu

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

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
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HLL Biotech Limited

Name	Designation	Signature	Date
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**DATA SHEET**

**HLL BIOTECH LIMITED, CHENNAI**

<b>nne pharmaplan®</b>	<b>INTEGRATED VACCINES COMPLEX, CHENGALPATTU</b>		 <p><b>HLL BIOTECH LIMITED</b> <small>(Subsidiary of HLL Lifecare Limited, A Government of India Enterprise)</small></p>
	Equipment Name	Type I Ultra pure water system	
	Project #	120310	
	Document #	DS-MQW	

**1 Process requirements**

1.1 Type I Ultra pure water system is used to generate ultra pure water which used in Quality control department for various buffer/solution preparation

**2 Equipment ID**

2.1 Q1-MQW 01

**3 Technical Specification**

3.1	Model	Bench top model with energy saving operation mode,Built in automatic self cleaning/Sanitization and Volume control dispensing
3.2	Dispense Flow rate	Up to 2.0 lpm
3.3	Output Conductivity @ 25°C	0.055µS/cm
3.4	Output TOC, ppb	<5
3.5	Output Bacterial count, cfu/ml	<1 CFU / ml
3.6	Resistivity / Inorganics at 25°C	18.2MΩ•cm
3.7	Bacterial Endotoxin (Pyrogens)	<0.001 Eu/ml
3.8	PH	Neutral (Vendor to specify)
3.9	RNase	< 2pg/ml
3.10	DNase	< 20 pg /ml
3.11	Feed water pressure	Vendor to specify
3.12	Feed water Temperature	5-35°C
3.13	Feed water Quality	Soft water
3.14	Noise Level	< 65 db at a distance of 1 metre.
3.15	Voltage	100-240 V
3.16	Frequency Range	50-60 Hz +/- 10%
3.17	Earth Ground	The power source must be earth grounded ( Client scope)

**4 Material of Construction**

4.1 Vendor to specify

**5 Specific Equipment requirement**

5.1 The equipment shall be compatible for cleaning with all standard disinfectants.

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5.2	Training/demo for users on operations shall be provided.		
5.3	The apparatus shall be closed container to avoid external contaminant.		
5.4	Easy and convenient to operate		
5.5	The apparatus shall be autoclavable		
<b>6</b>	<b>Other requirement</b>		
6.1	The equipment must be easy to clean and shall be compatible for cleaning with all standard disinfectants		
6.2	Training for the users must be provided.		
<b>7</b>	<b>Regulatory aspects</b>		
7.1	CE certification		
<b>8</b>	<b>Safety requirements</b>		
8.1	Appropriate closure of all parts.		
8.2	On power failure equipment should come in fail safe condition		
<b>9</b>	<b>Documents</b>		
9.1	<b>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</b>		
9.2	IOQ Protocol.		
9.3	Operation and maintenance manuals shall be provided along with IQ and OQ documents during installation at site		
9.4	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.		
9.5	Warranty Letter for Minimum 1 year.		
9.6	Vendor should provide list of standard spare parts with ordering information.		
9.7	Vendor should provide list of change parts (if applicable) with ordering information		
<b>10</b>	<b>Timelines</b>		
	Not Applicable		
	<b>NOTE:</b> Accurate size and technical specification need to be mentioned by the vendor		
<b>11</b>	<b>Preffered List of Makes</b>		
11	MILLIPORE,ELGA,SIEMENS		

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**TABLE NO: 1**

EQUIPMENT ID	Room Name	Room No	Room dimension in mm	Room height in mm
Q1-MQW 01	Microbiology Lab	Q1S045	3700x4600 1400x2650	2400

**Table-2: Change Log**

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

**Table-3: Annexure**

Not applicable

