

Equipment Specification Data Sheet

Equipment Name: Sterility Test Apparatus

Document No.: DS-STA 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-STA 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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Equipment Specification Data Sheet

HLL Biotech Limited, Chennai

HLL Biotech Limited Sterility Test Apparatus	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		
	Equipment Name:	Sterility Test Apparatus	
	Project #	120310	
	Document #	DS-STA 01	

1	Process requirements	
1.1	This equipment is used for closed system for sterility testing.	
2	Equipment ID	
2.1	Q1-STA 01	
3	Technical Specification	
3.1	Model	cGMP,CE marking ,completely closed system
3.2	Type	Fully automated
3.3	Accessories required	<i>As per vendor spec</i>
3.4	Quantity	01 nos
3.5	Material of Construction	SS 316 L
3.6	Screen	<i>Should contain a LCD screen NMT 11 cm</i>
3.7	Software	<i>Software should hold a test method library more than 200 test method protocol</i>
3.8	Compatibility	The canister should be compatible with the product
4	Material of Construction	
4.1	Outer Body	<i>Vendor to specify</i>
5	Specific Equipment requirement	
5.1	Should be fit in both horizontal and vertical class A Laminar flow hoods	
5.2	Should be a software control peristaltic pump	
5.3	The pump should not release any particles or microbes into the cleanroom or isolator environments or cause turbulence in laminar flow uni	
5.4	Should have a pressure control system	
5.5	Should display audio visual alert in case of pressure	
5.6	Power supply pack should contains ports for foot switch,syringe support and USB port for SOP transfer to pump.	
5.7	Membrane integrity should be displayed and equal splitting efficiency should be displayed.	
5.8	Should be able to give operators step by step assistance throughout the testing procedure	
5.9	Ampoule breaker should be available for ampoules	

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nne pharma plan	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		
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6	Other requirement
6.1	The equipment should be easy to use and clean.
7	Regulatory guidelines / standards
7.1	System should comply 21 CFR part 11 compliance
7.2	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.
10	Timelines
10.1	Not Applicable
11	Preferred list of Make
11.1	Millipore, Sartorius
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

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HLL Biotech Limited, Chennai

nne pharmaplan*	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 <small>HLL BIOTECH LIMITED Subsidiary of HLL Micro Limited A Company of Public Concern</small>
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TABLE NO: 1

Equipment ID	Block Name	Room Name	Room No
Q1-STA 01	Admin, QA & QC	Sterility lab-2	Q1S067

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
29-10-2015	Tushar	00	-	New document

Table-3: Annexure

Not applicable
