

Equipment Specification Data Sheet

Equipment Name: Sterility Test Apparatus

Document No.: DS-STA 01

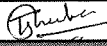
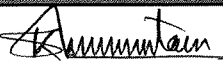
Revision: 00

Project No.: 120310


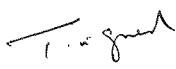

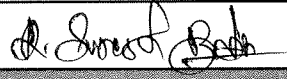
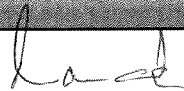
Project Name: Integrated Vaccines Complex,
Chengalpattu

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

NNE Pharmaplan India Limited


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

HLL Biotech Limited


Name	Designation	Signature	Date
Reviewed by			
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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	As per vendor spec
3.4	Quantity	01 nos
3.5	Material of Construction	SS 316 L
3.6	Screen	Should contain a LCD screen NMT 11 cm
3.7	Software	Software should hold a test method library more than 200 test method protocol
3.8	Compatibility	The canister should be compatible with the product
4	Material of Construction	
4.1	Outer Body	Vendor to specify
5	Specific Equipment requirment	
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	he pump should not release any particles or microbes into the cleanroom or isolator environments or cause turbulence in laminar flow un	
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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HLL Biotech Limited, Chennai		
nne pharmaplan*	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 cGMP 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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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
