

Equipment Specification Data Sheet

Equipment Name: Microbiological Air Sampler for compressed air and gases.

Document No.: DS-MSA 01




Revision: 00

Project No.: 120310




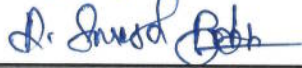

Project Name: Integrated Vaccines Complex,
Chengalpattu

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

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
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HLL Biotech Limited

Name	Designation	Signature	Date
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Project Authority RAMAN - K. R	CEO		04-11-2016

Equipment Specification Data Sheet

HLL Biotech Limited Chennai

nne pharmaplan®

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

Equipment name Microbiological Air Sampler for compressed air and gases.

Project # 120310

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1 Process requirement

1.1 It is used to sample the compressed air and gases in clean room for microbiological testing.

2 Equipment ID

2.1 Q1-MSA 01-02

3 Technical Specification

3.1 Model cGMP compliant

3.2 Flow rate 100 ltr/minute

3.3 Sample Volume 1000 litres

3.4 Expected Operational Hours per Day / Shift Continuous Duty.

3.5 Sieves/Sampling head Should be made of SS and sterilisable.

3.6 Size of petri plates compatible Should comply for RODAC and 90mm plates

3.7 External dimension (W X D X H mm) Vendor to specify based on the above mentioned capacities.

3.8 Accessories Should have Self contained unit consisting of connections, air flow meter, pressure gauge, tap, funnel head complete with plate housing

3.9 Quantity 2 Nos

3.1 Power requirement To be compatible without power supply.

4 Material of Construction

4.1 Body Construction Interior cGMP compliant

4.2 Exterior cGMP compliant

4.3 All welds shall be ground finish.

5 Specific Equipment requirement

5.1 Suitable to sample both compressed air and gases.

5.2 Require flow meter and sample flow rate controller.

5.3 Equipment shall be designed to fully transportable.

5.4 The design of the equipment shall facilitate efficient and easy cleaning.

5.5 The equipment shall autoclaveable..

5.6 Compatible for cleaning with all standard disinfectants.

5.7 The Equipment shall be collect air samples on 90 mm Petri plate.


6 Other requirement

6.1 Training/demonstration to be provided to users.

7 Regulatory guidelines / standards

7.1 CE Certification

8 Safety requirements

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HLL Biotech Limited Chennai					
nne pharma plan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU			 HLL BIOTECH LIMITED <small>(A Subsidiary of HLL Pharma Limited)</small> <small>(A Government of India Enterprise)</small>	
	Equipment name	Microbiological Air Sampler for compressed air and gases.			
	Project #	120310			
	Document #	DS/MSA 01			
8.1	Noise level should not be more than 60 decibels from a distance of 1 m from equipment.				
8.2	No sharp edges/Corners, crevices in the equipment.				
9	Documents				
9.1	IQ/OQ documents.				
9.2	Instrument calibration certificate.				
9.3	Operation and maintenance manuals.				
9.4	List of standard spare parts with ordering information.				
9.5	Warranty for 1 year from the date of supply.				
10	Timelines				
	Not Applicable				
11	Preferred list of Makes				
11.1	SAS Super PINOCCHIO II				
	NOTE: Accurate size and technical specification need to be mentioned by the vendor				
Table-1: Equipment location					
Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1-MSA 01-02	Admin, QA & QC	Microbiology	Q1S045	3700X4600	2400
Table-2: Change Log					
Date	Name / Initial	Revision	Section	Change/Comment	
16.10.2016	RHSE	00	-	New Document	