

Equipment Specification Data Sheet

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

Document No.: DS-MSA 01

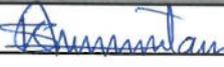
Revision: 00

Project No.: 120310

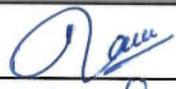
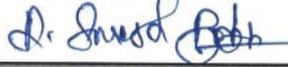
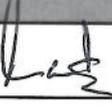
Project Name: Integrated Vaccines Complex, Chengalpattu

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
<b>Reviewed by</b>			
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Project Authority RAMAN - K. R	CEO		04-11-2016

**Equipment Specification Data Sheet**

**HLL Biotech Limited Chennai**

<b>nne pharmaplan®</b>	<b>INTEGRATED VACCINES COMPLEX, CHENGALPATTU</b>		 <b>HLL BIOTECH LIMITED</b> <small>(A Subsidiary of HLL Universal Limited)                  A Government of India Enterprise</small>
	Equipment name	Microbiological Air Sampler for compressed air and gases.	
	Project #	120310	
	Document #	DS/MSA 01	

<b>1</b>	<b>Process requirement</b>	
1.1	It is used to sample the compressed air and gases in clean room for microbiological testing.	
<b>2</b>	<b>Equipment ID</b>	
2.1	Q1-MSA 01-02	
<b>3</b>	<b>Technical Specification</b>	
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.
<b>4</b>	<b>Material of Construction</b>	
4.1	Body Construction	Interior
4.2		Exterior
4.3	All welds shall be ground finish.	
<b>5</b>	<b>Specific Equipment requirement</b>	
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.	
<b>6</b>	<b>Other requirement</b>	
6.1	Training/demonstration to be provided to users.	
<b>7</b>	<b>Regulatory guidelines / standards</b>	
7.1	CE Certification	
<b>8</b>	<b>Safety requirements</b>	

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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.
<b>9 Documents</b>	
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.
<b>10 Timelines</b>	
	Not Applicable
<b>11 Preferred list of Makes</b>	
11.1	SAS Super PINOCCHIO II
	<b>NOTE:</b> 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