

Equipment Specification Data Sheet

Equipment Name: Air Sampler

Document No.: DS-ASA 01

Revision: 01

Project No.: 120310

Project Name: Integrated Vaccines Complex,  
Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
Q1	Admin, QA & QC	Q1-ASA 01-12	-	12

**NNE Pharmaplan India Limited**

Name	Designation	Signature	Date
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**Prepared by**

Ms. Niharika Ruhela	Process Engineer	for <i>Sandeep</i>	11-02-2016
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**Checked by**

Mr. Yogesha M J	Process Engineer	<i>yogesha m j</i>	11/02/2016
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**Approved by**

Dr. Harshad Mali	Lead - Process Engineer	for <i>Harshad Mali</i>	11/02/2016
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**HLL Biotech Limited**

Name	Designation	Signature	Date
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**Reviewed by**

User department: SANJEEV KUMAR R	Manager	<i>SK</i>	15/02/2016
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Project / Engineering department VIGNESH KARAN T	DM PROJECTS	<i>T. Vignesh</i>	15/2/16
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**Approved by**


Head of the department V. SIVAKANESH	Manager	<i>V. Sivakanesh</i>	15/02/2016
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Head of the department (QA) A. SURESH BABU	DM - Q.C & QA	<i>A. Suresh Babu</i>	17.02.2016
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**Authorized by**

RAMAN K. R.	C.E.-O.	<i>Raman K. R.</i>	19-2-16
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Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name:	Air Sampler
	Project #	120310
	Document #	DS-ASA 01
		
1	<b>Process requirements</b>	
1.1	This equipment is used for microbial monitoring of total suspended air borne particulates in clean rooms/sterile environments	
2	<b>Equipment ID</b>	
2.1	Q1-ASA 01-12	
3	<b>Technical Specification</b>	
3.1	Model	cGMP with CE marking
3.2	Type	Portable
3.3	Accessories required	SS 316 aspirating head,Battery pack,Battery charger,integrated port for data transfer and carry case.
3.4	Quantity	12 nos
3.5	Noise level	50 dBA to 1 meter
3.6	Remote control	Interval sampling,delayed start can be followed by infrared remote control
3.7	Sampling program	50-9999 litres
3.8	Sample volume	1000 litres
3.9	Display	LCD display with alphanumeric keypad
3.10	Battery	Chargeable battery
3.11	Battery Life	5-8 hrs
3.12	Airflow	100-300 litres/minute
3.13	Sampling time	5-10 minutes
3.11	Weight	Not more than 3 kg
3.12	Charger	100-200 V charger
3.13	Connectors	Connectors are protected from corrosive gas or liquid with folding caps.
3.14	Dimensions	A per user requirement
3.15	Sampling grid	Stainless steel 316 L,Autoclavable
3.16	Software compliance	21 CFR Part 11 compliance
3.17	Keyboard	Alpha nematic keyboard
4	<b>Material of Construction</b>	
4.1	Outer Body	As per vendor specification.
5	<b>Specific Equipment requirement</b>	
5.1	Design avoids turbulence in unidirectional air flow and re-aspiration of tested air in accordance with ISO specifications.	
5.2	Real time with date and calibration reminder	
5.3	Should have integrated mass flow sensor	
5.4	Fully comply national and international standards for environmental monitoring	
5.5	Low running cost & operational flexibility	
5.6	100% sampling efficiency	
5.7	The equipment shall be able to withstand the mechanical stresses.	
5.8	Customisable for different sample volumes	
5.9	Multiple language choice	
5.10	The equipment should be provided with handle to carry from one place to other place easily.	
6	<b>Other requirement</b>	
6.1	The equipment should be easy to use and clean.	
6.2	All bolts,nuts on the exterior part of equipment should be with cap head or cap nut	
6.3	There should be no crevices,so as to avoid dust accumulation.	
7	<b>Regulatory guidelines / standards</b>	
7.1	The equipment shall be as per cGMP standards.	

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8	<b>Safety requirements</b>	
8.1	Appropriate closure of all parts	
8.2	On power failure equipment should come in failsafe condition	
9	<b>Documents</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:	
9.1	IQ/OQ/PQ validation documentation/onsight activation	
9.2	Operation and maintenance manuals	
9.3	Calibration certificate should be provided	
9.4	One year Warranty letter.	
9.5	List of standard spare parts with ordering information.	
9.5	Onsite calibration / other terms of calibration	
9.6	Training for the technical persons to be included to handle the equipment.	
10	<b>Preferred list of makes</b>	
	Merck Millipore, AES(Biomerieux), SAS	
11	<b>Timelines</b>	
	Not Applicable	
	<b>NOTE:</b> Accurate size and technical specification need to be mentioned by the vendor	

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nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU			 <b>HBL</b> HLL BIOTECH LIMITED <small>(Subsidiary of HLL Micros Limited)            (A Government of India Enterprise)</small>	
	Equipment Name: Air Sampler				
	Project # 120310				
	Document # DS-ASA 01				
TABLE NO: 1					
Equipment ID	Block Name	Room Name	Room No	Room Dimension	Room Height in mm
Q1-ASA 01-12	Admin, QA & QC	Micribiology lab	Q1S045	-	-
Table-2: Change Log					
Date	Name	Revision	Section	Change/Comment	
07-10-2015	Niharika Ruhela	00	-	New document	
26-10-2015	Niharika Ruhela	01	All	Updated as per comments given by HBL dated 13-10-2015	
Table-3: Annexure					
Not applicable					

