

## DATASHEET

### HLL LIFECARE LIMITED, CHENNAI

#### REVIVAL OF BCG VACCINE LABORATORY GUINDY, CHENNAI

nne pharmaplan®

#### ONLINE PARTICLE COUNTER



PROJECT #:	110729
EQUIPMENT ID #:	FG-OPC 01
DOCUMENT # :	DS/FG-OPC 01

<b>1</b>	<b>Process requirements</b>	
1.1	It is used for the continuous monitoring of the air borne particles in the critical areas of the Vial filling line.	
<b>2</b>	<b>Technical Specification</b>	
2.1	Channels	Two channel mode :0.5µm and 5.0µm,
2.2	Standard Flow rate	1.0ft³/ min
2.3	Zero Count filter	0.2 micron absolute with tubing on all sensors
2.4	Maximum particle concentration	<b>Vendor shall specify</b>
2.5	Vacuum Source	Internal vacuum pump with suitable motor
2.6	Sampling Probe	<b>Vendor shall specify the size</b>
2.7	Laser Diode	Class 1 Laser Devices
2.8	Calibration	ISO21501-4 required
2.9	Software	<b>Vendor shall specify the software</b>
2.10	PC for software	<b>Software control with remote monitoring.</b>
2.11	Dimension (W x H x D)	<b>Vendor to specify</b>
2.12	Electrical Requirement	<b>Vendor to specify</b>
2.13	Output	RS-232, ethernet and facility for monitoring and controlling.
2.14	Weight	<b>Vendor to specify</b>
<b>3</b>	<b>Material Of Construction</b>	
3.1	Enclosure Box	SS 316L - passivated
3.2	Isokinetic Probe	SS 316L ( Only for Lyoloading area particle counter)
3.3	Probe holder	SS 304
3.4	Tube	FDA approved
<b>4</b>	<b>Specific Requirements</b>	
4.1	Number of sensors : Five numbers which should be fixed in the following areas of filling area <ul style="list-style-type: none"> <li>• Infeed/ Turn table</li> <li>• Filling Station</li> <li>• Stoppering station</li> <li>• Lyophiliser Loading/ unloading LAF (Ceiling suspended LAF)</li> <li>• Vial Sealing Machine</li> </ul>	
4.2	Pump shall have HEPA filter at exhaust	
4.3	Blower shall shut off if system detects sample probe capped while pump is ON	
4.4	The system shall include all associated hardware, cabinet and required license	
4.5	Flow rate indicator: Differential Pressure transducer with LED indicator	
4.6	Four Visual indicators on the front of the unit: LED power, count, laser status and flow status	
4.7	The system shall be Capable to generate a variety of standard reports defined by industry standards, such as EU GMP Annex 1 (2008) or FS 209E.	
4.8	Sensor Mounting bracket shall be provided	
4.9	Vendor to consider and quote for the following: Data acquisition / logging cable and tubing laying/ termination. Computer, computer hardware and printer. (The particle counter system cables should run through separate duct)	
4.10	The cable shall be insulated to prevent the loss of data.	



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4.11	Vendor to provide the computer with following minimum specification Monitor - 14 inch RAM - 4 GB Hard drive - 200 GB Processor- intel i3-3220 Processor (3M cache, 3.30 GHz) It shall be compatible with windows xp, Windows 7 and Windows 8 or latest operating system.					
<b>5</b>	<b>Other requirements</b>					
5.1	SS Isokinetic probe and SS probe holder only for Lyoloading/Unloading particle counter shall be provided.					
5.2	Automatic shut off shall be provided					
5.3	System shall have communication cable - RS 232 or RJ45 ethernet cable.					
5.4	Tricolor alarm tower shall be integrated to all the sensors and the required hardware shall be provided.					
5.5	Vendor shall provide the option to monitor the flow rate continuously both in cubic foot and cubic meter					
5.6	Provision to mount the isokinetic sampling probe at a maximum distance of 1 feet away from the point of risk to product.					
<b>6</b>	<b>Regulatory aspects</b>					
6.1	21CFR part 11 compliance					
6.2	The system shall be compliance with ISO standards and CE standards					
6.3	Factory Prime calibration with NIST traceable standards in accordance with ASTM F-328 and JIS 9921 Exceeds ISO21501					
<b>7</b>	<b>Safety requirements</b>					
7.1	In the event of equipment / system malfunction or loss of utilities, the unit must contain all necessary protection devices to ensure that the equipment / system and the article remain in a safe condition.					
7.2	Proper earthing of the equipment.					
<b>8</b>	<b>Documents</b>					
8.1	DQ Document					
8.2	IQ / OQ Protocol					
8.3	Operational Manual					
8.4	MOC certificates					
8.5	List of MAKE with certificate (to be used during fabrication of this unit)					
8.6	Cable line diagram to be provided by vendor.					
<b>9</b>	<b>Timelines</b>					
	NA					
	<b>NOTE:</b> Accurate size and technical specification need to be mentioned by the vendor.					
	AFI Approved for Enquiry			AFO Approved for Ordering		
02	2014-12-19	MJY	SDBB	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1/2

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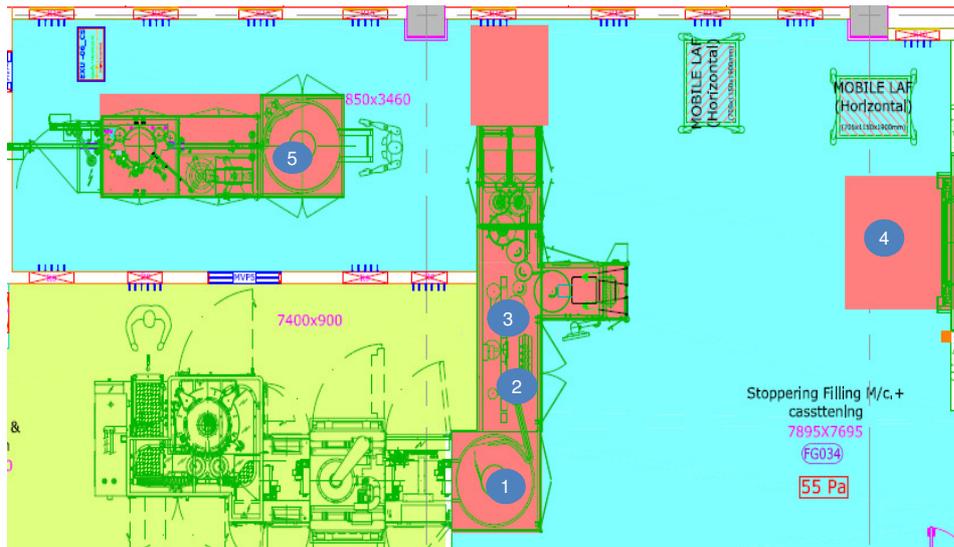


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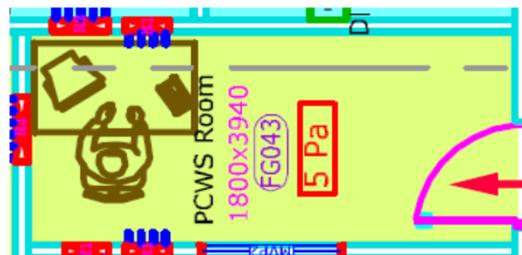
SENSOR AREAS, GROUND FLOOR

ROOM NUMBER:	FG034
ROOM DIMENSIONS	L(7895mm) X W(7695mm) L(3945mm) X W(4415mm)
FALSE CEILING HEIGHT	3000mm
ROOM PRESSURE	55 Pa

Particle counter No.	Location
1	In-Feed Turn Table
2	Vial Filling station
3	Vial Stoppering Station
4	Lyophiliser Loading/ unloading LAF
5	Vial Sealing Machine



GROUND FLOOR, PCWS ROOM	
ROOM NUMBER:	FG043:
ROOM DIMENSIONS	L(1800mm) X W(3940mm)
FALSE CEILING HEIGHT	2400mm
ROOM PRESSURE	5 Pa



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