

**DATASHEET**  
**HLL BIOTECH LIMITED, CHENNAI**

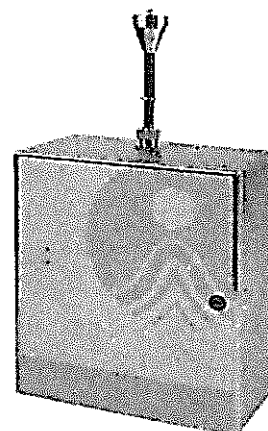
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**REVIVAL OF DPT VACCINE MANUFACTURING  
FACILITY, PII, COONOR**

**ONLINE PARTICLE COUNTER**

PROJECT #:	110831
EQUIPMENT ID #:	FG-OPC 01
DOCUMENT # :	DS/FG-OPC 01

1	Process requirements	Vendors Comments
1.1	It is used for the continuous monitoring of the air borne particles in the critical areas of the Vial filling line.	
2	Technical Specification	
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 sensorrs
2.4	Maximum particle concentration	<i>Vendor shall specify</i>
2.5	Vacuum Source	Internal vacuum pump with suitable motor
2.6	Sampling Probe	<i>Vendor shall specify the size</i>
2.7	Laser Diode	Class 1 Laser Devices
2.8	Calibration	ISO21501-4 required
2.9	Software	<i>Vendor shall specify the software</i>
2.10	PC for software	<i>Software control with SCADA base for remote monitoring.</i>
2.11	Dimension (W x H x D)	<i>Vendor to specify</i>
2.12	Electrical Requirement	<i>Vendor to specify</i>
2.13	Output	RS-232/ethernet with SCADA facility for monitoring and controlling.
2.14	Weight	<i>Vendor to specify</i>
3	Material Of Construction	
3.1	Enclosure Box	SS 304
3.2	Isokinetic Probe	SS 316
3.3	Probe holder	SS 304
3.4	Tube	cGMP/FDA compliant
4	Specific Requirements	
4.1	Number of sensors : Four numbers. The sensors 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>• Capping station</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	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.	
4.7	Sensor Mounting bracket shall be provided.	



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
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4.8	Vendor to consider and quote for the following: Data acquisition software/ logging cable, control panel and tubing laying/ termination. Computer, computer hardware and printer (inkjet, colour). (The particle counter system cables should run through separate duct. The distance between computer and sensor will be 50 RMT)					
4.9	The cable shall be insulated to prevent the loss of data.					
4.10	Vendor to provide the computer with following minimum specification Monitor - 14 inch RAM - 4 GB Hard drive - 1 TB Processor- intel i3/higher					
5	<b>Other requirements</b>					
5.1	SS Isokinetic probe and SS probe holder on the machine shall be provided.					
5.2	System shall have communication cable - RS 232/RJ45/ethernet cable.					
5.3	Tricolor alarm (1 no) tower shall be integrated to all the sensors and the required hardware shall be provided.					
5.4	Vendor shall provide the option to monitor the flow rate continuously both in cubic foot and cubic meter					
6	<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					
7	<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.					
8	<b>Documents</b>					
8.1	DQ Document					
8.2	IOQ Protocol					
8.3	Operational Manual					
8.4	MOC certificates					
8.5	Comprehensive 1 year warranty from the date of completion.					
8.6	Cable line diagram to be provided by vendor.					
9	<b>Timelines</b>					
	2 months from the date of issue of purchase order					
	<b>NOTE:</b> Accurate size and technical specification need to be mentioned by the vendor.					
	AFI Approved for Enquiry			AFO Approved for Ordering		
0	2017-04-08	MJY	SDBB	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1/2
NNE Pharmaplan		Prepared By	Name: Designation:			Sign & Date:
		Approved By	Name: Designation:			Sign & Date:
HLL Biotech Limited		Reviewed By	Name: Designation:			Sign & Date:

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	ONLINE PARTICLE COUNTER		
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HLL Biotech Limited	DOCUMENT #:	DS/FG-OPC 01	
Pasteur Institute of India	Approved By	Name: <i>Harshad</i> Designation: <i>Manager (Projects)</i>	Sign & Date: <i>For</i> <i>S. Yawar</i> <i>25/4/17</i>
	Reviewed By	Name: Designation:	Sign & Date:
	Reviewed By	Name: Designation:	Sign & Date:
	Approved By	Name: Designation:	Sign & Date:

Formulation - OK - B. S. S. / 24/4/17  
*S. M.*  
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