

DATA SHEET

HLL BIOTECH LIMITED, CHENNAI

nne pharmaplan®	REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOOR		 <small>HLLBIOTECH LIMITED (Subsidiary of HLL Lifecare Limited) (A Government of India Enterprise)</small>
	UV-visible Spectrophotometer		
	PROJECT NO	110831	
	EQUIPMENT ID	Annexure 1	
	DOCUMENT NO	DS-SPM- 01	

1	Process requirements	
1.1	UV-visible spectrophotometer is used for the measurement of transmittance or reflectance absorbed by a sample at a given wavelength.	
2	Technical Specification	
2.1	Model	cGMP complaint
2.2	Type	UV visible spectrophotometer
2.3	Spectrum Band Width	1nm
2.4	Wavelength Range	190 - 1100nm
2.5	Wavelength accuracy	±0.1 nm at 656nm D2
2.6		±0.3 nm (190 - 1100 nm)
2.7	Lamp source	Xenon flash lamp/halogen lamp/deuterium lamp built in light source auto position adjustment.
2.8	Lamp interchange wavelength	Automatic interchange linked to wavelength
2.9	Wavelength length display	0.1 nm increments
2.10	Wavelength slew rate	about 6000nm per minute
2.11	Wavelength length scanning speed	2nm ~ 3000nm per minute
2.12	Wavelength reproductivity	lesser than ± 0.02nm
2.13	stray light	less than 0.02% NaI at 220 nm, NaNO ₂ at 340 nm, less than 1.0% KCl at 198 nm.
2.14	Photometric system	Double Beam
2.15	Photometric measurement modes	Absorbance,transmittance,Concentration
2.16	Photometric ranges	Absorbance -4 to 4 Abs
2.17		Transmittance 0% to 400%
2.18		Concentration ± 9999 °C
2.19	Photometric Accuracy	< ±0.005 Abs at 440.0,465.0,546.1,590.0 and 635.21 nm,1 Abs (NIST 930e), <±0.01 Abs at 235,257,313,350,430 nm (Potassium dichromate,EP method)
2.20	Photometric repeatability	< ±0.001 Abs at 0.5 Abs, < ±0.001 Abs at 0.1 Abs,< ±0.003 Abs at 2 Abs
2.21	Photometric noise	<0.00005 Abs(700 nm)
2.22	Photometric stability	<0.001 Abs/hr at 0Abs, 340nm after one hour warm up.Measured over 1 hr, Every 5 seconds constant ambient temp
2.23	Base line stability	<0.0003 Abs/hr at 0 Abs(700nm,1 hr after light source turned on).
2.24	Base line flatness	<0.0001 Abs 0.5 seconds blank, 0.5 seconds rms
2.25	Software	Vendor to be specify

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2.26	Weight	Vendor to be specify	
2.27	Dimension	Vendor to be specify	
2.28	Power required	Vendor to be specify	
3	Material of Construction		
3.1	Body	cGMP complaints	
3.2	Cuvettes	For Measurements in UV range : Quartz cuvettes standard size and 1ml size. For Measurements in the visible range : Glass standard size and 1 ml size	
3.3	Detector	Silicon photodiode	
4	Specific Equipment requirment		
4.1	It should display the Process curve section data.		
4.2	Open sample area shall be provided for convenient sample handling.		
4.3	Fast spectra scanning for complete spectral information and multi wavelength applications.		
4.4	It should have its clock for time and date stamps of the spectra.		
4.5	Extensive self test procedure should be provided that check the electronics and key optical to ensure consistent between validation.		
4.6	Display panel shall be supported to graphical representation with LCD back light and keypad shall be sealed membraned with tactile response keys.		
4.7	USB data port should be provided to transfer the data.Connectivity USB port for USB stick, Computer and Printer shall be provided.		
4.8	It should give automatic calculation of dilution factors.		
5	PC and Printer Requirements		
5.1	Type	Vendor to be specify	
5.2	HDD	Vendor to be specify	
5.3	Operating System	Vendor to be specify	
5.4	CPU	Vendor to be specify	
5.5	Video	Vendor to be specify	
5.6	RAM	Vendor to be specify	
6	Other requirement		
6.1	Main power ON/OFF switch on control panel		
7	Regulatory guidelines / standards		
7.1	The equipment shall be as per GLP or GMP standards.		
7.2	CE certification		

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8	Safety
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8.1	NA
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9	Documents
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	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.
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9.1	Operation and maintenance manuals
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9.2	One year Warranty.
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9.3	List of standard spare parts with ordering information.
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9.4	Calibration and inspection certificates. IOQ and PQ document to be provided.
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9.5	Training for the technical persons to be included to handle the equipment.
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10	Timelines
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	Not Applicable
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	NOTE: Accurate size and technical specification need to be mentioned by the vendor
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	AFI Approved for Enquiry	AFO Approved for Ordering		
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Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1 / 2
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	Project No :	110831	
	EQUIPMENT ID :	_____	
Document No:	DS-SPM- 01		

TABLE NO: 1

Equipment ID	Block Name	Quantity	Room Name	Room No	Room dimension in mm	Room height in mm
B1-SPM 01	Pertussis	1	IPQC	B1G018	2200 x 3310	3000
B1-SPM 02	Diphtheria	1	IPQC	B1G057	2200 x 3310	3000
B2-SPM 01	Tetanus	1	IPQC	B2G026	3200 x 5335	3000

	AFI Approved for Enquiry		AFO Approved for Ordering			Sheet 2/2
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