

Equipment Specification Data Sheet

Equipment Name: UV-Visible Spectrophotometer

Document No.: DS-SPM 02

Revision: 01

Project No.: 120310

Project Name: Integrated Vaccines Complex,  
Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
G1	Animal House	G1-SPM 01	-	1

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
<b>Prepared by</b>			
Mr. Sandeep Kumar	Process Engineer	<i>Sandeep</i>	26.02.2016
<b>Checked by</b>			
Mr. Sridhar Babu	Senior Engineer - Process	<i>K. Sridhar Babu</i>	26.02.2016
<b>Approved by</b>			
Dr. Harshad Mali	Lead Engineer - Process	<i>HM</i>	26.02.2016

HLL Biotech Limited

Name	Designation	Signature	Date
<b>Reviewed by</b>			
User department Bacterial Formulation	NA		
User department Rabies Bulk			
User department Animal House <i>K. Jagan Mohan Rao</i>	Deputy Manager	<i>K. Jagan Mohan Rao</i>	02.03.2016
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Head of the department Bacterial Formulation	NA		
Head of the department Rabies Bulk			
Head of the department Animal House <i>R. A. Lakshmi</i>	MANAGER	<i>R. A. Lakshmi</i>	02.03.2016
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<b>Authorized by</b>			
Project Authority <i>Ramesh K.R.</i>	C.E.O.	<i>Ramesh K.R.</i>	7-3-16

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HLL Biotech Limited, Chennai		
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	UV-Visible Spectrophotometer
	Document No.	DS-SPM 02
	Revision No.	01
1	<b>Process Requirement</b>	
1.1	UV-visible spectrophotometer is used for the measurement of transmittance or reflectance absorbed by a sample at a given wavelength.	
2	<b>Equipment ID</b>	
2.1	G1-SPM 01	
3	<b>Technical Specification</b>	
3.1	Model	cGMP complaint
3.2	Type	UV visible spectrophotometer
3.3	Spectrum Band Width	1nm to 1.5 nm
3.4	Wavelength Range	190 - 1100 nm
3.5	Wavelength accuracy	±0.1 nm at 656.1 nm D2
3.6		±0.3 nm (190 - 1100 nm)
3.7	Lamp sources	Xenon flash lamp/tungsten/halogen lamp/deuterium lamp built in light source auto position adjustment with life of average 1000 hours or better
3.8	Lamp interchange wavelength	Automatic interchange linked to wavelength
3.9	Wavelength length display	0.1 nm increments
3.10	Wavelength slew rate	about 6000nm per minute
3.11	Wavelength length scanning speed	2nm to 3000nm per minute
3.12	Wavelength reproductivity	lesser than ± 0.02nm
3.13	stray light	Less than 0.08% NaI at 220 nm, NaNO2 at 340 nm, less than 1.0% KCl at 198 nm.
3.14	Photometric system	Double Beam
3.15	Photometric measurement modes	Absorbance, Transmittance, Concentration
3.16	Photometric ranges	Absorbance -4 to 4 Abs.
3.17		Transmittance 0% to 400%
3.18		Concentration ± 9999.
3.19	Photometric Accuracy	< ±0.005 Abs at 440.0,465.0,546.1,590.0 and 635.1 nm,1 Abs (NIST 930e), <±0.01 Abs at 235,257,313,350,430 nm (Potassium dichromate, EP method )
3.20	Photometric repeatability	< ±0.001 Abs at 0.5 Abs, < ±0.001 Abs at 1.0 Abs,< ±0.003 Abs at 2 Abs.
3.21	Photometric noise	<0.00005 Abs(700 nm)
3.22	Photometric stability	<0.001 Abs/hr. at 0Abs, 340nm after one hour warm up. Measured over 1 hr. Every 5 seconds constant ambient temp
3.23	Base line stability	<0.0003 Abs/hr (700nm, 1 hr after light source turned on).
3.24	Base line flatness	<0.001 Abs 0.5 seconds blank, 0.5 seconds rms.
3.25	Software	Vendor to be specify.

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3.26	Weight	Vendor to specify.
3.27	Dimension	Vendor to specify.
3.28	Power requirement	To be compatible to standard Indian Power supply socket.
<b>4</b>	<b>Material of Construction</b>	
4.1	Body	cGMP complaints
4.2	Cuvettes	For Measurements in UV range: Quartz cuvettes standard size and 1ml size. For Measurements in the visible range: Glass standard size ad 1 ml size
4.3	Detector	Silicon photodiode/Photo multiplier
<b>5</b>	<b>Specific Equipment Requirements</b>	
5.1	It should display the Process curve section, data.	
5.2	Open sample area for convenient sample handling.	
5.3	Fast spectral scanning for complete spectral information and multi wavelength applications.	
5.4	Own clock for time and date stamps of the spectra.	
5.5	Extensive self-test procedures that check the electronics and key optical to ensure consistent performance between validations.	
5.6	Display panel shall be supported to graphical representation with LCD back light and keypad shall be sealed membrane with tactile response keys.	
5.7	USB data port should be provided to transfer the data. Connectivity USB port type A for USB Stick.USB port type B for Computer, USB port type A for printer.	
5.8	Data should be able to be printed with the help of printer.	
5.9	It should give automatic calculation of dilution factors.	
5.10	Equipment shall be compatible for cleaning with all standard disinfectants.	
<b>6</b>	<b>Other Requirement</b>	
7.1	Main power ON/OFF switch on control panel	
7.2	Training/Demo for the users on operation and cleaning to be provided.	
<b>7</b>	<b>Regulatory aspects</b>	
7.1	The equipment shall be as per GLP or GMP standards.	
7.2	CE certification	
<b>8</b>	<b>Safety Requirements</b>	
	Following facilities must be provided to protect personnel and equipment:	
8.1	Appropriate closure of all part.	
8.2	Proper earthing is necessary	
<b>9</b>	<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	IOQ document.	
9.2	Operation and maintenance manual shall be provided along with IOQ documents during Installation at site.	
9.3	Warranty letter for 1 year from the date of supply.	
9.4	List of standard spare parts with ordering information.	
9.5	Calibration certificate of critical instrument with respect to the traceable national reference standard instrument and their calibration procedure	

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10	Timelines	
10.1	Not Applicable	
11	Preferred list of Makes	
11.1	Shimadzu, Perkin Elmer, Agilent, Thermo Scientific	
NOTE: Accurate size and technical specification need to be mentioned by the vendor		

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<b>Table-1: Equipment location</b>					
Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
G1-SPM 01	Animal house	Lab Area (Challenge)	G1G078	4000x5000	2700
<b>Table-2: Change Log</b>					
Date	Name	Revision	Section	Change/Comment	
18-02-2016	Mr. Sandeep Kumar	00	-	New Document	
24-02-2016	Mr. Sandeep Kumar	01	-	Updated as per comments received from HBL on 22-02-2016	