





nne pharmaplan		HBL HLL BIOTECH LIMITED		
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	
Prepared by				
Mr. Sandeep Kumar	Process Engineer	<i>Sandeep</i>	26.02.2016	
Checked by				
Mr. Sridhar Babu	Senior Engineer - Process	<i>K. Sridhar Babu</i>	26.02.2016	
Approved by				
Dr. Harshad Mali	Lead Engineer - Process	<i>HM</i>	26.02.2016	
HLL Biotech Limited				
Name	Designation	Signature	Date	
Reviewed by				
User department: Bacterial Formulation				
User department: Rabies Bulk				
User department: <i>K. IPSHANTHAR</i>	<i>Deputy Manager</i>	<i>K. IPSHANTHAR</i>	02.03.2016	
Project / Engineering: <i>VIGNESHWARAN</i>	<i>DM - PROJECTS</i>	<i>V. Vigneshwaran</i>	29.02.2016	
Approved by				
Head of the department: Bacterial Formulation				
Head of the department: Rabies Bulk				
Head of the department: <i>Dr. Harshad Mali</i>	<i>MANAGER</i>	<i>R. A. Harshad Mali</i>	02.03.2016	
Head of the department: <i>Dr. Suresh Babu</i>	<i>DM</i>	<i>Dr. Suresh Babu</i>	04.03.16	
Authorized by				
Project Authority: <i>RANJAN K.R.</i>	<i>C.E.O.</i>	<i>Ranjana</i>	7-3-16	

Equipment Specification Data Sheet				
HLL Biotech Limited, Chennai				
nne pharma plan*		INTEGRATED VACCINES COMPLEX, CHENGALPATTU		
		Equipment Name	UV-Visible Spectrophotometer	
		Document No.	DS-SPM 02	
		Revision No.	01	
1	Process Requirement			
1.1	UV-visible spectrophotometer is used for the measurement of transmittance or reflectance absorbed by a sample at a given wavelength.			
2	Equipment ID			
2.1	G1-SPM 01			
3	Technical Specification			
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.
4	Material of Construction	
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
5	Specific Equipment Requirements	
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.	
6	Other Requirement	
7.1	Main power ON/OFF switch on control panel	
7.2	Training/Demo for the users on operation and cleaning to be provided.	
7	Regulatory aspects	
7.1	The equipment shall be as per GLP or GMP standards.	
7.2	CE certification	
8	Safety Requirements	
	Following facilities must be provided to protect personnel and equipment:	
8.1	Appropriate closure of all part.	
8.2	Proper earthing is necessary	
9	Documents	
	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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Table-1: Equipment location					
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
Table-2: Change Log					
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	