

Equipment Specification Data Sheet

Equipment Name: Polarimeter

Document No.: DS-POL 01

Revision: 02

Project No.: 120310

Project Name: Integrated Vaccines Complex,
Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
Q1	Admin QA & QC	Q1-POL 01	-	1

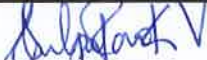
NNE Pharmaplan India Limited

Name	Designation	Signature	Date
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Prepared by

Mr. Kiran Kumar M S	Engineer - Process		8/6/15
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Checked by

Ms. Shilpa Rao	Senior Engineer - Process		8/6/15
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Approved by


Mr. Vikas Katial	GM - Projects(SME) & Head COC Vaccines		9/6/15
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HLL Biotech Limited

Name	Designation	Signature	Date
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Reviewed by

Sanjeev Kumar R	Manager		12/6/15
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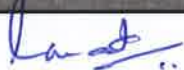
Polina Sreenath	Deputy Manager		12/6/15
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Approved by


V. Sivaganesan	Manager		19/6/15
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R. Suresh Babu	DM		22/6/15
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Authorized by

Raman K. Ramachandran	CEO		24/6/15
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HLL Biotech Limited, Chennai		
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	Polarimeter
	Document No.	DS-POL 01
	Revision No.	02
		
1	Process requirements	
1.1	Polarimeter is used to measure the angle of rotation caused by passing polarized light through an optically active substance.	
2	Equipment ID	
2.1	Q1-POL-01	
3	Technical Specification	
3.1	Model	Vendor to specify
3.2	Type	Automatic
3.3	Display panel	color LCD/ LCDTouch screen
3.4	Measuring scales	Optical Rotation, Specific Rotation, concentration
3.5	Measurement Range	Optical Rotation ± 89.9 , specific Rotation ± 999.99 %, Concentration 0-99.9%
3.6	Measurement Accuracy	± 0.01
3.7	Communication	3 USB port, RS 232, Ethernet port
3.8	Repeatability	± 0.01
3.9	Resolution	± 0.001
3.10	Temperature Range	20-45 °C
3.11	Wavelength	589nm
3.12	Light Source	Tungsten Halogen Lamp/ LED
3.13	Tube Length	100/200 mm
3.14	Temperature sensor	Pt 100
3.15	Prism	Glan Thomson Calcite
3.16	Power required	To be compatible to standard Indian Power supply sockets.
4	Material of Construction	
4.1	Body	Epoxy powder coated non-reactive, corrosion resistant
4.2	Detector	Photo Multiplier Tube (PMT)
5	Specific Equipment requirement	
5.1	It must measure and display angle of rotation (AOR), International Sugar Scale (ISS), specific optical rotation, concentration, and purity.	

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	Equipment Name	Polarimeter	
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5.2	Password security should be provided to protect the data from accidental deletion		
5.3	Automatic temperature compensation should be provided for correct readings of the International Sugar Scale from 64 to 86°F (18 to 30°C).		
5.4	The fast mode should be provided to adjust the polarimeter for an approximate reading by continuously rotating the analyzer		
5.5	Auto self-calibrate.		
5.6	21 CFR Part 11 compliance		
5.7	Equipment shall be compatible for cleaning with all standard disinfectants.		
6	Other requirement		
6.1	It must have capacity to save the data for 100 measurements.		
6.2	USB port should be provided for access		
6.3	LCD display should be provided for process monitoring and alarm indicator.		
6.4	Report generation and storage should be possible.		
6.5	Training / Demo for the users on the operation and cleaning to be provided.		
7	Regulatory aspects		
7.1	CE Certification		
8	Safety requirements		
	Following facilities must be provided to protect personnel and equipment:		
8.1	Appropriate closure of all parts.		
8.2	Proper earthing should be given for the instrument.		
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 documents		
9.2	Operation and maintenance manuals shall be provided with IOQ documents during installation at site.		
9.3	Warranty letter for 1 year from the date of supply.		
9.4	Calibration certificate of critical instruments 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	Rudolph, Anton paar, Perkin Elmer.		
	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
Q1-POL 01	Admin QA&QC	Chemical Lab / Bio Chemistry	Q1S022	6250×7350	2400
Table-2: Change Log					
Date	Name	Revision	Section	Change/Comment	
11-03-2014	Kiran Kumar M S	00	-	New document	
27-10-2014	Kiran Kumar M S	01	All	Updated as per comments received from HBL dated 15-10-2014	
06-01-2015	Kiran Kumar M S	02	All	Updated as per comments given by HBL team during meeting dated 06-01-2015 at HBL office	
Table-3: Annexure					
Not applicable					