

Equipment Specification Data Sheet

Equipment Name: Refractometer

Document No.: DS-REF 01




Revision: 03

Project No.: 120310






Project Name: Integrated Vaccines Complex,
Chengalpattu


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


NNE Pharmaplan India Limited


Name	Designation	Signature	Date
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HLL Biotech Limited

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Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
HLL Biotech Limited Integrated Vaccines Complex, Chengalpattu	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	Refractometer
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1	Process requirements	
1.1	A refractometer is used for measurement of index of refraction (refractometry).	
2	Equipment ID	
2.1	Q1-REF-01	
3	Technical Specification	
3.1	Model	Vendor to specify
3.2	Type	Digital and Automatic
3.3	Display	LCD / LED Touch Screen
3.4	Measurement scales	Refractive Index (nD), Brix (% sucrose) and upto 100 custom programmed scales
3.5	Measurement Range	Refractive index $\pm 1.26 - 1.70$, Brix 0 - 100
3.6	Resolution	Refractive index ± 0.0001 , Brix ± 0.01
3.7	Reproducibility	Refractive index ± 0.0001 , Brix ± 0.1
3.8	Accuracy	Refractive index ± 0.0001 , Brix ± 0.1
3.9	Light source	Tungsten Halogen Lamp/ LED
3.10	Optical Wavelength	589nm
3.11	Sample Dish	Synthetic sapphire flat prism
3.12	Temperature Range	15 °C to 85 °C
3.13	Response time	> 2 seconds
3.14	Temperature Reproducibility	± 0.01 °C
3.15	Ambient Temperature Limit	5 °C to 40 °C
3.16	Sample Temperature Limit	25 °C to 250 °C
3.17	Temperature Correction Range	4 °C to 95 °C
3.18	Power requirement	To be compatible with standard Indian power supply sockets
4	Material of Construction	
4.1	Body	Epoxy powder coated corrosion resistant
5	Specific Equipment requirement	
5.1	It must display Refractive Index (RI), BRIX (% sucrose) Temperature Correction BRIX, Temperature Correction RI and 10 to 15 User Programmable Scales.	
5.2	Built-in peltier temperature control that eliminates the need for a water bath circulator.	
5.3	Password security should be provided for data.	
5.4	Automatic temperature compensation should be provided to corrects readings 18°C to 40°C for pure Sucrose solution.	
5.5	Automatic temperature equilibration detection software should be provided on each model to ensure that the sample and prism temperature is stable and should provide accurate and precise measurements.	

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5.6	Extensive diagnostics, error detection and display with audio visual alarm system for deviation.		
5.7	The equipment shall be compatible for cleaning with all standard disinfectants.		
6	Other requirement		
6.1	It shall have capacity to save the data for 100 measurements.		
6.2	3 USB port shall be provided for access.		
6.3	LCD display shall be provided for process monitoring and alarm indicator.		
6.4	Download the Data to computer or printer.		
6.5	Training/Demo for the users on operating and cleaning to be provided.		
7	Regulatory aspects		
7.1	The equipment shall be as per cGMP standards.		
7.2	All measurements are made automatically, which eliminates the need for operator judgment.		
7.3	Calibration with fluids traceable to NIST and calibration data securely stored and available for review.		
7.4	Operator Traceability, full 21 CFR Part 11 compliant password system.		
7.5	Verification step with electronic signature.		
7.6	CE Certification.		
8	Safety requirements		
	Following facilities must be provided to protect personnel and equipment:		
8.1	Proper earthing should be given for the instrument.		
8.2	Appropriate closure of all parts.		
8.3	Adjustable down stopper to prevent accidental damage to slides.		
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 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 instruments with respect to the traceable national reference standard instrument and their procedure.		
10	Timelines		
10.1	Not Applicable		
11	Preferred list of Makes		
11.1	Rudolph, Perkin Elmer, Anton Paar, Cyber Lab		
	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	Admin QA&QC	Chemical Lab / Bio Chemistry	Q1S022	6250×7350	2400
Table-2: Change Log					
Date	Name	Revision	Section	Change/Comment	
13-03-2014	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	
29-04-2015	Kiran Kumar M S	03	All	Updated as per comments given by HBL team dated 27-02-2015.	
Table-3: Annexure					
Not applicable					