

Equipment Specification Data Sheet

Equipment Name: ELISA Reader

Document No.: DS-ELR 02

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
G1	Animal house	G1-ELR 01	-	1
Q1	Admin,QA and QC	Q1-ELR 01	-	1

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
Prepared by			
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Checked by			
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Approved by			
Dr. Harshad Mali	Lead Engineer - Process	<i>tu</i>	19/02/16

HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
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HLL Biotech Limited, Chennai			
nne pharmaplan*	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 HBL <small>HLL BIOTECH LIMITED (a subsidiary of HLL Lifescare Limited) (A Government of India Enterprise)</small>
	Equipment Name	ELISA Reader	
	Document No.	DS-ELR 02	
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1	Process requirements		
1.1	Fully Automatic ELISA readers are designed to detect antigen and antibodies in biological samples for immuno assays.		
2	Equipment ID		
2.1	G1-ELR 01		
2.2	Q1-ELR 01		
3	Technical Specification		
3.1	Microplate type	96/384 wells	
3.2	System	Monochrometer Based System.	
3.3	Visible Absorbance	Between 200 nm to 999 nm	
3.4	Temperature Range	Ambient 5 °C to 45 °C	
3.5	Wavelength range	200 nm to 999 nm	
3.6	Wavelength accuracy	0 to 3.0 OD	
3.7	Wavelength Bandwidth	vendor to specify	
3.8	Wavelength selection	Monochrometer tunable 1nm increments	
3.9	Photometric Method	Single and Dual wavelength	
3.10	Photometric range	0.000 to 3.500 OD	
3.11	Photometric Accuracy	0 to 3.0 OD	
3.12	Photometric Precision (Repeatability) (0 - 2.0 OD)	< ± 1.0% and ± 0.005 OD	
3.13	Photometric linearity(405 nm)	0 to 3.000 OD	
3.14	End point Read time	15 sec for 96 well	
3.15	Kinetic Read time	9 seconds minimum intervals	
3.16	Light source	Tungsten/Halogen/Xenon lamp(minimum average life time more than 1000 hours)	
3.17	Electrical requirement	To be compatible to standard Indian Power supply socket.	

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3.18	Detectors	vendor to specify	
3.19	Resolution	0.001 OD	
4	Material of Construction		
4.1	Main body	cGMP complaiance	
5	Specific Equipment requirment		
5.1	Suitable ELISA reader software should be provided for data analysis.		
5.2	Printed test plate comparison data sheet should be provided to compare the data obtained by microplate reader at specific wavelenght for accuracy.		
5.3	The equipment shall be compatible for cleaning with all standard disinfectants.		
6	Other requirement		
6.1	Appropriate training to be given for our employees to operate the equipment		
6.2	Vendor shall provide the option to record the data.		
6.3	Should be compatible with standard cleaning agents.		
6.4	Training/Demo for the users on operating 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	Proper earthing of the equipment		
8.2	Appropriate closure of all parts		
9	Documents		
	Following documents, but not limited to these,are expected from the vendor as part of the supply package in the hard copy as well as electronic file.		
9.1	IOQ document.		
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	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.		
9.5	Absorbance test plate certification.		
10	Timelines		
10.1	Not Applicable		

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11	Preferred list of Makes		
11.1	Molecular Devices, Biotek, Biorad, 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-ELR 01	Animal house	Lab Area-Testing	G1G055	4700 X 7300	2700
Q1-ELR 01	Admin,QA and QC	Immuno chemical Lab	Q1S026	5360 X 5520	2400
Table-2: Change Log					
Date	Name	Revision	Section	Change/Comment	
10-02-2016	Ms. Niharika Ruhela	00	-	New document	
Table-3: Annexure					
Not applicable					