

Equipment Specification Data Sheet

Equipment Name: ELISA Reader

Document No.: DS-ELR 01

Revision: 02

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
<b>Prepared by</b>			
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<b>Checked by</b>			
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HLL Biotech Limited

Name	Designation	Signature	Date
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HLL Biotech Limited, Chennai		
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
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	Document No.	DS-ELR 01
	Revision No.	02
		
1	<b>Process requirements</b>	
1.1	Fully Automatic ELISA readers are designed to detect antigen and antibodies in biological samples for immuno assays.	
2	<b>Equipment ID</b>	
2.1	G1-ELR-01	
2.2	Q1-ELR-01	
3	<b>Technical Specification</b>	
3.1	Microplate type	6 - 384 wells
3.2	System	Monochrometer Based System.
3.3	Dyanamic Range	0-4.0 OD
3.4	Temperature Range	Ambient 4 °C to 45 °C
3.5	Wavelength range	200 nm to 999 nm
3.6	Wavelength accuracy	< ± 0.003 OD ±1.0%, 0-2.0 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	Monochromator Wave lengt accuracy	± 2 nm
3.11	Photometric Accuracy	<±0.006 OD to ± 1.0 %, 0 to 2.0 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	12 sec for 96 well
3.15	Kinetic Read time	9 seconds minimum intervals
3.16	Temperature uniformity micro plate	± 0.5°C at 37°C well to well
3.17	Light source	Xenon lamp or Better (minimum average life time more than 1000 hours)
3.18	Electrical requirement	To becompatible to standard Indian Power supply socket.
3.19	Detectors	vendor to specify
3.20	Resolution	0.0001 OD




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<b>4</b>	<b>Material of Construction</b>	
4.1	Main body	cGMP complaince
<b>5</b>	<b>Specific Equipment requirment</b>	
5.1	Suitable ELISA reader software should be provided for data analysis.	
5.2	Fully automatic functioning.	
5.3	Printed test plate comparison data sheet should be provided to compare the data obtained by microplate reader at specific wavelength for accuracy.	
5.4	The equipment shall be compatible for cleaning with all standard disinfectants.	
<b>6</b>	<b>Other requirement</b>	
6.1	Automatic shut off shall be provided	
6.2	Appropriate training to be given for our employees to operate the equipment	
6.3	Vendor shall provide the option to record the data.	
6.4	Robotic Compatible shall be provided	
6.5	Should be compatible with standard cleaning agents.	
6.6	PC is required.	
6.7	Training/Demo for the users on operating and cleaning to be provided.	
<b>7</b>	<b>Regulatory aspects</b>	
7.1	CE Certification	
<b>8</b>	<b>Safety requirements</b>	
	<b>Following facilities must be provided to protect personnel and equipment:</b>	
8.1	Proper earthing of the equipment	
8.2	Appropriate closure of all parts	
<b>9</b>	<b>Documents</b>	
	<b>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.</b>	
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.	
<b>10</b>	<b>Timelines</b>	
10.1	Not Applicable	



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<b>11</b>	<b>Preferred list of Makes</b>		
11.1	Molecular Devices, Biotek, Biorad, Thermo scientific		
	<b>NOTE:</b> 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-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
<b>Table-2: Change Log</b>					
Date	Name	Revision	Section	Change/Comment	
11-07-2014	Niharika Ruhela	00	-	New document	
07-01-2015	Yogesha M J	01	All	Updated as per comments given by HBL team during meeting dated 07-01-2015 at HBL office	
04-05-2015	Niharika Ruhela	02	All	Changed as per comments received from clients on 27-02-2015	
<b>Table-3: Annexure</b>					
Not applicable					