

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 Pharamplan India Limited


Name	Designation	Signature	Date
Prepared by			
Ms. Niharika Ruhela	Engineer - Process		6/7/2015
Checked by			
Mr. Sridhar Babu	Senior Engineer - Process		6/7/2015
Approved by			
Mr. Vikas Katial	GM - Projects (SME) & Head COC Vaccines		6/7/2015


HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
K. YASWANTH REDDY	DM		9/7/2015
R. SANJEEV KUMAR	Manager		8/7/2015
Polina Sreenath	Deputy Manager		8/7/2015
Approved by			
Dr. K. A. ARUL ANAND	Manager		9/7/2015
V. SIVAGANESH	Manager		10/7/2015
R. SURESH BABU	DGM		10/7/2015
Authorized by			
Kamran. K. Ramachandran	CEO		13/7/2015

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne pharmanplan	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	ELISA Reader
	Document No.	DS-ELR 01
	Revision No.	02
 HLL BIOTECH LIMITED <small>(Subsidiary of HLL Micros Limited) A Division of HLL Biotech</small>		
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 400 nm and 700 nm
3.4	Temperature Range	Ambient 4 °C to 45 °C
3.5	Wavelength range	400 nm to 700 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	Photometric range	0.000 to 3.500 OD
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	Tungsten/Halogen/Xenon lamp(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	0.001 OD

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4	Material of Construction	
4.1	Main body	cGMP compliance
5	Specific Equipment requirement	
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.	
6	Other requirement	
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.	
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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HLL Biotech Limited, Chennai			
nne pharmanplan*	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 HLL BIOTECH LIMITED <small>(subsidiary of HLL Lifesciences Limited) A Government of India Enterprise</small>
	Equipment Name	ELISA Reader	
	Document No.	DS-ELR 01	
	Revision No.	02	
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			

Equipment Specification Data Sheet					
HLL Biotech Limited, Chennai					
nne pharmaplan	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 HBL <small>HLL BIOTECH LIMITED Subsidiary of HLL (Public Sector) (A Government of India Enterprise)</small>		
	Equipment Name	ELISA Reader			
	Document No.	DS-ELR 01			
	Revision No.	02			
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	
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	
Table-3: Annexure					
Not applicable					

Equipment Specification Data Sheet

Equipment Name: ELISA Plate Washer

Document No.: DS-ELW 01

Revision: 02

Project No.: 120310

Project Name: Integrated Vaccines Complex,
 Chengalpattu

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

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
Prepared by			
Ms. Niharika Ruhela	Engineer - Process	<i>N. Ruhela</i>	6/7/2015
Checked by			
Mr. Yogesha M J	Engineer - Process	<i>Yogesha M J</i>	6/7/2015
Approved by			
Mr. Vikas Katial	GM - Projects (SME) & Head COC Vaccines	<i>V. Katial</i>	6/7/2015

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Chengalpattu

HLL Biotech Limited


Name	Designation	Signature	Date
Reviewed by			
Sangeet Kumar	Manager	Sge	8/7/2015
Yashwanth Reddy	Deputy Manager	Yashwanth Reddy	9/7/2015
Polima Sreenath	Deputy Manager	Polima	8/7/2015
Approved by			
Sriharish . V	Manager	Sriharish	10/7/2015
Dr. K. A. Anil Anand	Manager	K. A. Anil Anand	10/7/2015
Suresh babu . R	DUM	S. Suresh Babu	10/7/2015
Authorized by			
Raman . K. Ramachandran	CEO	Raman	13/7/2015

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	ELISA Plate Washer
	Document No.	DS-ELW 01
	Revision No.	02
		
1	Process requirements	
1.1	The microplate washer is designed and shall be for washing various types of standard 96-well microtitre plates and 384 well microtitre plates, microstrips and microarrays for ELISA and related applications.	
2	Equipment ID	
2.1	G1-ELW-01	
2.2	Q1-ELW-01	
3	Technical Specification	
3.1	Manifold	8 and 12
3.2	Washing Wells	Must be suitable for washing all 96/384 wells of different bottoms- flat, round bottomed, U or V shapes. Must also be programmable to wash particular rows/columns.
3.3	Wash mode	Strip and plate
3.4	Fluid Inlets	Two fluids inlets with additional programming capabilities
3.5	Dispense Precision	± 5%
3.6	Wash cycles	Vendor to specify
3.7	Processing speed	Depends upon number of cycles up to 9 times
3.8	Vacuum	Integrated vacuum pump, 9 L/min
3.9	Aspiration time	Vendor to specify
3.10	Aspiration maximum residual volume in a well	< 2 µL per well
3.11	Volume range	50 to 300 µL per well
3.12	Soaking time	0 to 60 minutes
3.13	Shaking time	0 to 60 minutes
3.14	Bottle volume	2000 mL
3.15	Microprocessor controlled program	Required
3.16	Display	Front display panel with soft touch keys
3.17	Software	Create ,Edit and Run multiple protocols.Programmable automatic washing
3.18	Dimension (W x H x D)	Vendor to specify
3.19	Power Requirement	To be compatible to standard Indian Power Supply socket
3.20	Weight	Vendor to specify

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	Equipment Name	ELISA Plate Washer	
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4	Material of Construction		
4.1	Enclosure Box	Vendor to specify	
4.2	Wash Heads	SS 304	
5	Specific Equipment requirement		
5.1	The unit shall be designed for use in closed rooms with relative humidity 15-85% and temperature 10 °C to 35 °C.		
5.2	Reliable positive-displacement dispense pump that assures accurate and consistent dispensing.		
5.3	Aspiration to be facilitated with a vacuum pump		
5.4	Choice of 3 washing liquid bottles(1 for wash,1 for rinse and 1 for waste)		
5.5	Automated plate platform and washing head movement		
5.6	Unit to allow bottom washing and overflow washing		
5.7	Allow Manifold changeability in minutes		
5.8	Soft-touch keys on the display panel are used to create and store up to 50 user-defined programs.		
5.9	Programmable horizontal and vertical needle positions should be provided.		
5.10	8 and 12 channel autoclavable adaptors (for filling and washing) shall be provided.		
5.11	Equipment shall be compatible for cleaning with all standard disinfectants		
6	Other requirement		
6.1	Automatic shut off shall be provided		
6.2	Training/Demo for the users on operation and cleaning to be provided		
6.3	System shall have communication cable - RS 232 or RJ45 ethernet cable		
6.4	Vendor shall provide the option to monitor the flow rate continuously		
7	Regulatory aspects		
7.1	CE certification		
8	Safety requirements		
	Following facilities must be provided to protect personnel and equipment.		
8.1	In the event of equipment / system malfunction or loss of utilities, the unit must contain all necessary protection devices to ensure that the equipment / system and the article remain in a safe condition		
8.2	Appropriate closure of all parts.		
8.3	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 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 date of supply.		

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9.4	Calibration certificate of critical instrument with respect to the traceable national reference standard instrument and their calibration procedures.	
10	Timelines	
10.1	Not Applicable	
11	Preferred list of Makes	
11.1	Bio-Rad, Biotek , Thermo Scientific	
	NOTE: Accurate size and technical specification need to be mentioned by the vendor	



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	Equipment Name	ELISA Plate Washer			
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