

Equipment Specification Data Sheet

Equipment Name: KTA ELISA READER

Document No.: DS-KER 01

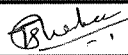

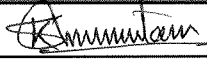
Revision: 00

Project No.: 120310


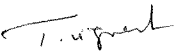

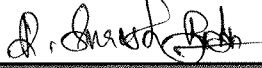

Project Name: Integrated Vaccines
Complex, Chengalpattu


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


NNE Pharmaplan India Limited

Name	Designation	Signature	Date
Prepared by			
Mr. Tushar Shinde	Engineer - Process		11/02/2016
Checked by			
Mr. Yogesha M J	Process Engineer		11/02/2016
Approved by			
Dr. Harshad Mali	Lead - Process Engineer	for 	11/02/2016

HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
SANJEEV KUMAR .R	Manager		15/02/2016
VIGNESHKARAN .T	DM, PROJECTS		15/2/16
Approved by			
V. SIVAGANESH	Manager		15/02/2016
R. SURESH BABU	DM, Q.C & Q.A		17.02.2016
Authorized by			
RAMAN K. R.	C. E. O		19.2.16

Equipment Specification Data Sheet			
HLL Biotech Limited Chennai			
nne pharma plan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 HBL HLL BIOTECH LIMITED (Subsidiary of HLL Vaccine Limited) (A Government of India Enterprise)
	Equipment name	KTA ELISA READER	
	Project #	120310	
	Document #	DS-KER 01	
1	Process requirement		
1.1	This equipment is used for the quantity assay of endotoxin by kinetic LAL method for the in process samples and the finished product.		
2	Equipment ID		
2.1	Q1-KER 01		
3	Technical Specification		
3.1	Microplate type	standard 96-well plate	
3.2	Time require to process one specimen	Venedor to specify	
3.3	Sensitivity	Vendor to specify	
3.4	Model	cGLP compliant	
3.5	Operating temperature	18 °C to 40 °C	
3.6	Operating humidity	20% to 80% non condensing	
3.7	Absorbance range	Venedor to specify	
3.8	Method	Quantitative	
3.9	Reagent and Kit Required	Vender to specify	
3.10	Type of assay	Vendor to specify	
3.11	Emergency stop	Required	
3.12	Display	2 Line/24 character LCD	
3.13	Software used	Vendor to specify	
3.14	Reader	Vendor to specify	
3.15	Linearity	Vendor to specify	
3.16	Measurement speed	Vendor to specify	
3.17	Temperature control	Vendor to specify	
3.18	Accuracy	Vendor to specify	
3.19	Filter capacity	Vendor to specify	
3.20	Weight	Not more than 16 kg	
3.21	Light source	Vendor to specify	
3.22	Type	Table top	
3.23	Dedicated PC for the equipment	Not Required	
3.24	Reading speed	Single wavelength/Double wave legth with 12 or 20 seconds	
3.25	External dimension (W X D X H mm)	Vendor to specify based on the above mentioned capacities	
3.26	Power consumption	Vendor to specify	

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3.27	Power requirement (kW)	To be compatible to standard indian power supply socket	
4	Material of Construction		
4.1	Body Construction	Interior	cGLP compliant
4.2		Exterior	cGLP compliant
4.3	All welds shall be ground finish		
5	Specific Equipment requirment		
5.1	Customizable endotoxine test report		
5.2	Edit assay features which allows for the correction of template layout mistakes		
5.3	Multilanguage support for installation,user interface,reports and user help and manual		
5.4	The design of the equipment shall facilitate efficient and easy cleaning.		
5.5	The system should have the ability to check the quality of test results and to validate it		
5.6	The equipment shall be compatible for cleaning with all standard disinfectants.		
5.7	Database storage for all the data		
5.8	Software shall be identify trend and product quality, and eliminate manual report modification.		
5.9	System should capable of trouble shoot whenever required with secured link.		
6	Other requirement		
6.1	Training/demonstration to be provided to users		
7	Regulatory guidelines / standrds		
7.1	System should comply 21 CFR part 11 compliance		
7.2	The equipment shall be as per cGLP standards.		
8	Safety requirements		
8.1	Vendor to specify		
8.2	No sharp edges/Corners, crevices in the equipment.		
9	Documents		
9.1	IOQ		
9.2	Operation and maintenance manuals shall be provided along with IOQ documents during installation at site.		
9.3	List of standard spare parts with ordering information.		
9.4	Warranty for 1 year from date of supply.		
10	Timelines		
	Not Applicable		
11	Preferred list of makes		
11.1	Charles River,Cape Cod,Lonza		
	NOTE: Accurate size and technical specification need to be mentioned by the vendor		

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HLL Biotech Limited Chennai

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INTEGRATED VACCINES COMPLEX, CHENGALPATTU

Equipment name KTA ELISA READER

Project # 120310

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TABLE NO: 1

EQUIPMENT ID	Block Name	Room Name	Room No	Room dimension	Room height in mm
Q1-KER 01	Admin, QA & QC	Immunochemistry lab	Q1S026	-	-

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
09-09-2015	Tushar Shinde	00	-	New document

Table-3: Annexure

Not applicable

