

# DATA SHEET

**HLL LIFECARE LIMITED, CHENNAI**

<b>nne pharmaplan®</b>	<b>REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOOR</b>		
	<b>Endotoxin detection kit</b>		
	<b>Project No</b>	<b>110831</b>	
	<b>Equipment ID</b>	<b>Q-EDK 01</b>	
	<b>Document No</b>	<b>DS/Q-EDK 01</b>	

<b>1</b>	<b>Process requirements</b>	
1.1	It is used for the detection of endotoxin detection level in the biopharmaceutical samples like vaccines. It is placed in QC lab. <b>(Room name: QC lab (GF), Room number: M1G039)</b>	
<b>2</b>	<b>Technical Specifications</b>	
	Endotoxin detection kit containing one number of Incubating Plate Readers, software and Kinetic Turbidimetric LAL Assays.	
<b>2.1</b>	<b>Incubating Plate Readers</b>	
2.1.1	Model	cGLP
2.1.2	Type	Fully automatic (96 well plates in 10 seconds)
2.1.3	Light source	Tungsten halogen bulb or Xenon flash lamp <b>(Vendor to specify)</b>
2.1.4	Dynamic range	0.000 to 4.000 Abs
2.1.5	Wavelength range	380 to 900 nm 340 to 900 nm (UV option)
2.1.6	Wavelength selection	Interference filters or <b>Vendor to specify</b>
2.1.7	Wavelength Bandwidth	2 nm
2.1.8	Accuracy	±1% ±0.010 Abs from 0.000 to 2.500 Abs ±2% ±0.010 Abs from 2.500 to 3.500 Abs
2.1.9	Standard filters	405, 450, 490, 630 405, 450, 490, 630, 340 (UV option)
2.1.10	Plate type	96 well microplates
2.1.11	Wavelength Repeatability	±0.5% ±0.005 Abs from 0.000 to 2.500 Abs ±1.5% ±0.005 Abs from 2.500 to 3.500 Abs ±2.5% ±0.005 Abs from 3.500 to
2.1.12	Photometric Resolution	0.001 OD
2.1.13	Temperature Range	Ambient + 4 °C up to 50 °C
2.1.14	Linearity	±1% from 0.000 to 2.500 Abs ±2% from 2.500 to 3.500 Abs
2.1.15	Reading speed	12 secs single wavelength 20 secs dual wavelength 5 secs kinetic single wavelength
2.1.16	Power supply	Vendor to specify
2.1.17	PC connection	USB
2.1.18	LED indicators	Power on, lamp on
2.1.19	Quantity	1
2.2	Dimensions	Vendor to specify
<b>3</b>	<b>Material of Construction</b>	
3.1	Body	Cast metal, ergonomic body with stain-resistant enamel finish.
<b>4</b>	<b>Specific Equipment requirements</b>	
<b>4.1</b>	<b>Incubating Plate Readers</b>	
4.1.1	Endotoxin detection range should be 0.01 EU/ml - 100 EU/ml.	
4.1.2	The Incubating Plate Readers must be portable and ergonomically designed to minimize bench space required.	
4.1.3	Incubating Plate Readers should be simple to use, and accuracy should be as stated in pion no. 2.8.	
4.1.4	There should be provision for monitoring of temperature-sensitive reactions with consistent temperature regulation from ambient to 50°C. As stated in point no. 2.13	
4.1.5	Incubating Plate Readers should be use with kinetic turbidimetric LAL assays and with Kinetic Chromogenic LAL Assays (Optinal).	
4.1.6	Preferably touch screen of the Incubating Plate Readers should be LED/ LCD digital display.	
4.1.7	Incubating Plate Readers should be compatible with data Acquisition & Analysis Software.	
4.1.8	<b>Accessories:</b> Contains 200 tests = 2 x 100 tests/vial lysate, 2 vials reconstitution buffer, 1 vial endotoxin	
<b>4.2</b>	<b>Compatible software</b>	
4.2.1	The software should be offers a fully integrated solution for quantitative endotoxin detection testing, data management and reporting needs.	
4.2.2	The software should be compatible with above stated reader.	
4.2.3	The software should allow multi-user control. (Multi user can control multiple readers from one work station)	
4.2.4	There should be provision for edit assay feature which allows for the correction of template layout mistakes.	
4.2.5	The software should have trending tool with features of generations of graphs, reports, day today result comparison.	
4.2.6	The software should have built-in database backup and maintenance scheduler.	
4.2.7	The software should able to generate automatic warning of errors in scheduled database tasks.	

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4.2.8	The software should be able to overwrite existing backup files to avoid filling backup drive. Before that it should give warning message to overwrite.
4.2.9	Software should be able to generate non-editable result sheet.
4.2.10	The software should support routine GLP functions such as password protection, results memory etc.
4.2.11	Software should meet 21 CFR Part 11 technical requirements for electronic records and signatures, audit trails and database archiving.
4.2.12	The software should have option for upgradable to new versions.

4.3	<b>Hardware and Software requirements:</b> ■ <b>Operating System:</b> Windows® XP Professional SP2 or higher; Windows Vista™ Business or Enterprise ■ <b>CPU:</b> Intel® Pentium® III 1GHz or higher. ■ <b>Memory:</b> 2 GB minimum ■ <b>Hard drive:</b> 4 GB or more available space
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**5 Other requirements**

5.1	Equipment should be integrated with printer, to analyse sample details.
5.2	Training for the technical persons to be included to handle and to operate the endotoxin detection kit.
5.3	Cleaning paper should be provided to clean optical surfaces.

**6 Regulatory aspects**

6.1	21 CFR Part 11 Compliance.
6.2	CE certification, ETL mark for UL3101-1.
6.3	CAN/CSA C22.2 No. 1010.1
6.4	RS 232 interface is required to transfer the data as well as to take the print out.
6.5	Data logging software to monitor and capture the critical data.

**7 Safety requirements**

7.1	Proper earthing should be provided
7.2	In the event of equipment malfunction or loss of utilities, the unit must contain all necessary protection devices to ensure that the equipment and the product remain in a safe condition.

**8 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
8.1	Operation and maintenance manuals.
8.2	NPL traceable Calibration certificates and calibration procedures
8.3	Vendor should provide IOPQ for software and readers.
8.4	Vendor should provide warranty Letter for Minimum 1 year, from the date of supply.
8.5	Vendor should provide list of standard spare parts with ordering information.
8.6	Vendor should provide list of change parts (if applicable) with ordering information

**9 Timelines**

9.1	<i>Not Applicable</i>
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**NOTE:** Accurate size and technical specification need to be mentioned by the vendor

AFI Approved for Enquiry		AFO Approved for Ordering			
0	2014.09.09	KNKS	SRKV	<input type="checkbox"/>	<input type="checkbox"/>
Rev	Date	Completed By	Checked By	AFI	AFO

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SI.NO.	Block Name	Room Name	Room No.	Block No.	Room Diminesion in mm	Room Height in mm	Qty.
1	Micro Biology	LAB	M1G039		3025X5050		1

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