

Equipment Specification Data Sheet

Equipment Name: Data Logger

Document No.: DS-DLG 01


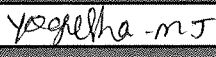
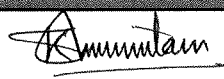
Revision: 00

Project No.: 120310


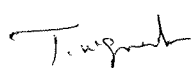

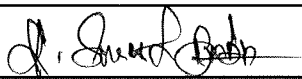

Project Name: Integrated Vaccines Complex,
Chengalpattu


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


NNE Pharmaplan India Limited

Name	Designation	Signature	Date
Prepared by			
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Checked by			
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Approved by			
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HLL Biotech Limited

Name	Designation	Signature	Date
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Equipment Specification Data Sheet			
HLL Biotech Limited, Chengalpattu			
nne pharmaplan*	INTEGRATED VACCINES COMPLEX		 <small>HLL BIOTECH LIMITED</small> <small>(Subsidiary of HLL Lifecare Limited)</small> <small>(A Government of India Company)</small>
	Equipment Name	Data Logger	
	Project #	120310	
	Document #	DS-DLG 01	
1	Process requirements		
1.1	The equipment is used to monitor and report various changes in the equipment and in the environmental condition over time.		
2	Equipment ID		
2.1	Q1-DLG 01		
3	Technical Specification		
3.1	Display	Trend/Bar graph/Digital display	
3.2	Screen	5.5 inch LCD display	
3.3	Software	compatible with windows 7 & 8	
3.4	Number of analog input	100 channels	
3.5	Sample rate	Minimum 1 seconds	
3.6	Inbuild storage	Minimum 1 GB	
3.7	Data download	USB/Memory card provision	
3.8	Power supply	100-240 V	
3.9	Battery back up	Built in battery	
3.10	Compliance	Should complies 21 CFR Part 11	
3.11	Certification	CE certification/Others if any	
3.12	Muliple language option	Vendor to specify	
3.14	Safety requirements	Vendor to specify	
3.15	Communication	Ethernet	
3.16	Thermocouples	T type	
4	Material of Construction		
4.1	Outer Body	As per vendor specification.	
5	Specific Equipment requirment		
5.1	Shoud have a customized mathematical function which includes basic calculation along with Square root,exponential,Log and power.		
5.2	Report generation shall be in both excel and PDF format		
5.3	Report shall be generated only by using authorised password.		
5.4	System should enable with mutilevel password with provision of audit trial ,signature function and password expiration time.		
5.5	Should have customized screens which includes graph,bar,trend,alarm list view,memory summary display, multipanel display, log display,message list view and seggration provisions for upper and lower values		

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5.6	Should have the provision to enter the batch details description and sensor identification description.		
5.7	T type thermocouple should have accuracy of 0.2°C for temperature range of 0 to 400°C and 0.1 for 0 to - 200°C		
5.8	The alarm type include minimum of high limit ,low limit ,difference high limit ,difference low limit,delay high limit and delay low limit.		
5.9	System should have overview display for viewing all channels and each groups.		
5.10	Should have the provision for auto mail syatem during alarm events,power failures and storage medium errors		
5.11	Should have adjustable clock with calendar function		
6	Other requirement		
6.1	The equipment should be easy to use and clean.		
6.2	All bolts,nuts on the exterior part of equipment should be with cap head or cap nut		
6.3	There should be no crevices,so as to avoid dust accumulation.		
7	Regulatory guidelines / standards		
7.1	The equipment shall be as per cGLP standards.		
8	Safety requirements		
8.1	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 hard copy as well as editable electronic file:		
9.1	IQ/OQ/PQ validation documentation/onsight activation		
9.2	Operation and maintenance manuals		
9.3	Calibration certificate should be provided		
9.4	One year Warranty letter.		
9.5	List of standard spare parts with ordering information.		
9.5	Onsite calibration / other terms of calibration		
9.6	Training for the technical persons to be included to handle the equipment.		
10	Preferred list of Make		
10.1	Eurotherm, Yokogawa, Honeywell		
11	Timelines		
	Not Applicable		
	NOTE: Accurate size and technical specification need to be mentioned by the vendor		


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	Equipment Name	Data Logger	
	Project #	120310	
	Document #	DS-DLG 01	

TABLE NO: 1

EQUIPMENT ID	Block Name	Room Name	Room No
Q1-DLG 01	Admin, QA & QC	Instrumentation lab	Q1S020

Table-2: Change Log

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

Table-3: Annexure

Not applicable
