nne pharmaplan*

HBL HLL BIOTECH LIMITED
(Subsidiary of HLL Lifecare Limited)
(A Government of India Enterprise)

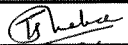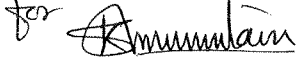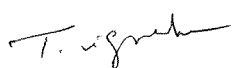| Equipment Specification Data Sheet	Equipment Name: Digital tele-thermometer with probes for pyrogen testing
Document No.: DS-DTT 01	**Revision: 00**
Project No.: 120310	**Project Name:** Integrated Vaccines Complex, Chengalpattu
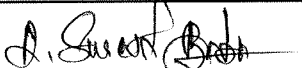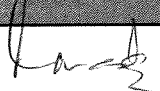
Block Code	Block Name	Identification No.	Capacity	Quantity
G1	Animal House	G1-DTT 01	-	1

NNE Pharmaplan India Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Tushar Shinde	Process Engineer	*(signature)*	11/02/2016
Checked by			
Mr. Yogesha M J	Process Engineer	Yogesha-m J	11-02-2016
Approved by			
Dr. Harshad Mali	Lead Engineer - Process	for *(signature)*	11/02/2016

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
K. YASWANTHA REDDY	Deputy Manager	*(signature)* Reddy	16.02.2016
VIGNESHWARAN.T	D M. PROJECTS	T. *(signature)*	16/2/16
Approved by			
Dr. K.A. *(signature)* ANAND	MANAGER	K.A. *(signature)*	16.02.2016
R. Sureeh Babu	DGM - QC R&A	R. *(signature)* Babu	17.02.2016
Authorized by			
RAMAN K. R.	C-E-O.	*(signature)*	19.2.16

Equipment Specification Data Sheet
HLL Biotech Limited, Chennai

nne pharmaplan	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL HLL BIOTECH LIMITED
	Equipment Name	Digital tele-thermometer with probes for pyrogen testing	
	Project #	120310	
	Document #	DS-DTT 01	

1	Process requirements	
1.1	It is an ideal, low cost, accurate and easy to operate instrument useful for Pyrogen testing in pharmaceutical industries. The instrument has verious channels so that temperature of different rabbits can be monitored simultaneously. Special temperature probes are provided which can be easily inserted in the anus of the rabbits. Any of the channels can be selected by a rotary switch provided on the front panel. The instrument is useful for pyrogen testing	

2	Equipment ID	
2.1	G1- DTT 01	

3	Technical Specification	
3.1	Range	0° to 70° C
3.2	Resolution	± 0.1° C
3.3	Accuracy	± 0.5 %
3.4	Channels	1- 6 channels, switch selectable
3.5	Repeatability	± 1.0° C
3.6	Display	Microprocessor based LED Display (Manual and Auto mode)
3.7	Input	RTD (PT-100) or IC Sensor
3.8	Probes	Minimum 06 Probes with 2 meter length cord
3.9	Power Supply	Vendor to specify

4	Material of Construction	
4.1	cGMP compliance	

5	Specific Equipment requirment	
5.1	The design of the equipment shall facilitate efficient and easy cleaning.	
5.2	The validation and calibration documents .	
5.3	The equipment shall be compatible for cleaning with all standard disinfectants.	
5.4	Easy training and implementation .	
5.5	Instrument should support fast response time (Quickly increasing or decreasing temperature measurements)	

6	Other requirement	
6.1	Instrment should accompanied by a PC for online data monitoring and printer for the data generation	
6.1	Operation and maintenance manuals shall be provided along with IOQ and PQ documents during installation at site	
6.2	List of standard spare parts with ordering information	
6.3	Warranty for 1 year from date of supply.	

7	Regulatory aspects	
7.1	CE Certification	

8	Safety requirements	

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne pharmaplan	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	HBL HLL BIOTECH LIMITED (Subsidiary of HLL Lifecare Limited) (A Government of India Enterprise)
	Equipment Name: Digital tele-thermometer with probes for pyrogen testing	
	Project #: 120310	
	Document #: DS-DTT 01	

8.1	proper earthing to instrument.
8.2	No sharp edges/Corners, crevices in the equipment.
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	calibration certificates
9.2	IOQ and PQ
9.3	manuals
10	**Timelines**
10.1	Not Applicable
11	**Preferred list of Makes**
11.1	Radix, Panomex, acumen Labware

TABLE NO: 1

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
G1- DTT 01	Animal house	Animal Room	G1G060	-	2700

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment

Table-3: Annexure

Not applicable