nne pharmaplan®

HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet

Equipment Name: Automatic Melting Points Apparatus

Document No.: DS-AMP 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-AMP 01	-	1

NNE Pharmaplan India Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Syed Sharique Ahmad	Process Engineer	Sharique	11.02.2016
Checked by			
Mr. Yogesha M J	Process Engineer	yogesha.m.j	11/02/2016
Approved by			
Dr. Harshad Mali	Lead - Process Engineer	for Ramanathan	11/02/2016

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
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Head of the department: V. SIVAGANESH Quality Control	Manager		15/02/2016
Head of the department (QA): R. SURESH BABU	DGM. Q.C & Q.A		19.02.2016
Authorized by			
RAMAN K.R.	C.E.O.		19.2.16

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		HBL
	Equipment Name	Automatic Melting Point Apparatus	
	Project #	120310	
	Document #	DS-AMP 01	

1	**Process requirements**	
1.1	A melting point apparatus is a scientific instrument used to determine the melting point of a substance	
2	**Equipment ID**	
2.1	Q1- AMP 01	
3	**Technical Specification**	
3.1	Model	cGLP (Compact and versatile)
3.2	Power supply	To be compatible to standard Indian Power Supply.
3.3	Display	Colour TFT
3.4	Determination Tempaerature Range	Ambient +10 °C to 400 °C
3.5	Operating Tempaerature	0 °C to 40 °C, non condensing
3.6	Heating up time 50 °C to 350 °C	Approx 4minutes
3.7	Cooling down time 350 °C to 50 °C	Approx 13 minutes
3.8	Temperature Resolution	0.1 °C
3.9	Ramp Temperature	0.1 °C to 20 °C per minute
3.1	Maximum Humidity	80%
3.11	Magnification Lens	2.5 X
3.12	No.of samples	Minimum 3 samples simultaneously
3.13	Sample Size	2 - 3 mm
3.14	Electrical Supply	100 to 240 V, 50 to 60 Hz
3.15	Dimension, (W X D X H)	Vendor to specify
3.16	Weight	Vendor to specify
3.17	Quantity	1 nos.
3.18	**Additonal Requirements**	
3.19	Temperature	a) In built temperature sensors for monitoring the melting and cooling tempaeratures b) Automatic temperature heating as per required for the process recipe c) Temperature regulators shall be provided to increase or decrease heating rates d) Automatic Heating Cut Off shall be provided for preventing the over heating of the system. e) In built thermometer shall be provided for on site temperature calibration.
3.20	Controls	a) Records can displayed on the front panel, printed, or transferred to a PC via USB. c)Samples can be viewed on the front panel through a removable magnification lens. c) Menu and settings with customizable security levels using password should be provided. d) The equipment should be able to store critical data with time for assessing the equipment performance and trouble shooting. e) Should provide real time result analysis. f) Should detects the start and completion of melting and stores the values by pressing a button. g) Touch key pads shall be provided for ease operation. h) User selectable operating modes shall be provided (automatic and mannual)
4	**Material of Construction**	
4.1	Body frame	cGLP Compliance
5	**Specific Equipment requirment**	
5.1	Appropriate failure detection and alarm notification	
5.2	Chamber shall be insulated properly to maintain inner environment	

5.3	Proper earthing is necessary.
5.4	Appropriate closure of all parts
6	**Other requirement**
6.1	Cleaning shall be done manually.
6.2	All bolts, nuts on the exterior part of system will be with cap head or cap nut.
6.3	Vendor to give code numbers for each component
6.4	All parts of the system exposed in classified area must be resistant to standard disinfectants or vendor shall provide the name of specific disinfectants
6.5	Agate mortar and pestel for homogenization sample.
6.6	Melting Point Capillaries
6.7	Optional Printer for results of calibration, melting and boiling point determination.
6.8	Software MeltingPoint Monitor or PC with
6.9	Sample gauge for measuring the sample size
6.10	Long glass tube with rubber stopper for packing the samples tightly.
6.11	Optional Keyboard for a fast input of sample parameters.
7	**Regulatory aspects**
7.1	cGLP compliances.
7.2	CE certification
8	**Safety requirements**
8.1	Always follow appropriate laboratory practices when using this equipment.
8.2	Appropriate closure of all parts.
8.3	On power failure equipment should come in fail safe condition
8.4	Noise level should not be more than 60 decibels at the distance of 1m from the equipment
9	**Documents**
9.1	**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**
9.2	IOQ Protocol.
9.3	Warranty Letter for 1 year from the date of supply.
9.4	Operation and maintenance manuals shall be provided along with IQ and OQ documents during installation at site
9.5	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
9.6	All equipment warranty should be valid for one year from the date of completion.
9.7	Vendor should provide list of standard spare parts with ordering information.
9.8	Vendor should provide list of change parts (if applicable) with ordering information
10	**Timelines**
10.1	Not Applicable
11	**Preferred list of Makes**
11.1	Stuart Equipment, Stanford Research System, Koehler Instrument
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

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TABLE NO: 1

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1- AMP 01	Admin, QA & QC	Chemical / Biochemical lab	Q1S022	-	-

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
09-09-2015	Syed Sharique Ahmad	00	-	New document

Table-3: Annexure

Not applicable