

Equipment Specification Data Sheet

Equipment Name: Deep Freezer

Document No.: DS-DPF 02

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity (L)	Quantity
Deep Freezer- Low Temperature				
B4	Rabies Vaccine bulk Production	B4-DPF 01	300	1
B4	Rabies Vaccine bulk Production	B4-DPF 02	100	1
G1	Animal House	G1-DPF 02	500	1
Q1	Admin QA & QC	Q1-DPF 04	300	1
Q1	Admin QA & QC	Q1-DPF 05	300	1
Q1	Admin QA & QC	Q1-DPF 11,12	300	2
P1	Secondary packing	P1-DPF 01	300	1
Deep Freezer- Ultra Low Temperature				
B4	Rabies Vaccine bulk Production	B4-DPF 03	500	1
B4	Rabies Vaccine bulk Production	B4-DPF 04	500	1
G1	Animal House	G1-DPF 01	200	1
Q1	Admin QA & QC	Q1-DPF 01-02	300	2
Q1	Admin QA & QC	Q1-DPF 03	300	1
Q1	Admin QA & QC	Q1-DPF 06	300	1
Q1	Admin QA & QC	Q1-DPF 07-08	300	2
Q1	Admin QA & QC	Q1-DPF 9-10	300	2
F1	Viral Vaccine Formulation	F1-DPF 01-02	300	2

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NNE Pharmaplan India Limited			
Name	Designation	Signature	Date
<b>Prepared by</b>			
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<b>Checked by</b>			
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<b>Approved by</b>			
Dr. Harshad Mali	Lead Engineer - Process	<i>hm</i>	19/02/16
HLL Biotech Limited			
Name	Designation	Signature	Date
<b>Reviewed by</b>			
User department: Rabies Bulk <i>P. Navin Kumar</i>	DEPUTY MANAGER	<i>P. Navin Kumar</i>	03.03.16
User department: Animal House <i>R. Jagan Mohan Reddy</i>	Deputy manager	<i>R. Jagan Mohan Reddy</i>	02.03.16
User department: Quality Control <i>Sandeep Kumar-R</i>	Manager	<i>Sgk</i>	29/02/16
User department: Viral Vaccine <i>B. SATHESH</i>	MANAGER-F(VV)	<i>Bm</i>	28.02.16
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<b>Approved by</b>			
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Head of the department: Animal House <i>Dr. R. Jagan Mohan Reddy</i>	MANAGER	<i>R. Jagan Mohan Reddy</i>	03.03.16
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Head of the department: Viral Vaccine Formulation <i>Dr. J. Jagan Mohan Reddy</i>	Project head (VV)	<i>Dr. J. Jagan Mohan Reddy</i>	03.03.16
Head of the department (Quality Assurance) <i>Dr. J. Jagan Mohan Reddy</i>	QCM	<i>Dr. J. Jagan Mohan Reddy</i>	04.03.16
<b>Authorized by</b>			
Project authority <i>K.R.</i>	C.E.O	<i>K.R.</i>	7.3.16

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne pharmanplan	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		
	Equipment Name	Deep Freezer- Low Temperature	
	Document No.	DS-DPF 02	
	Revision No.	0	
1	Process Requirements		
1.1	It is used to store material at low temperature		
2	Equipment ID	Capacity (L)	Type
2.1	B4- DPF 01	270 (minimum)	Vertical
2.2	B4- DPF 02	90 (minimum)	Vertical
2.3	G1-DPF 02	500 (minimum)	Vertical
2.4	Q1-DPF 04	270 (minimum)	Vertical
2.5	Q1-DPF 05	270 (minimum)	Vertical
2.6	Q1-DPF 11,12	270 (minimum)	Vertical
2.7	P1-DPF 01	270 (minimum)	Vertical
3	Technical Specification		
3.1	Model	cGMP compliant	
3.2	Operating Temperature	-20°C	
3.3	External dimension (W X D X H mm)	Vendor to specify based on the above mentioned capacities.	
3.4	Internal dimension (W X D X H mm)	Vendor to specify based on the above mentioned capacities.	
3.5	Shelves (W X D mm)	Removable shelves, no.of shelves vendor to specify based on capacity ( minimum 3-5 nos to be provided) Shelves. For 90 L Deep freezer (Vendor to specify)	
3.6	Height between the shelves (mm)	Refer Annexure- 1. Vendor to specify based on the above mentioned capacities.	
3.7	Outer Door type	Single door	
3.8	Compressor Type	Hermetic compressor shall be provided	
3.9	Refrigerant	CFC free(non flammable)	
3.10	Temperature precision (setting resolution)	± 0.5 °C	
3.11	Temperature resolution	± 0.1 °C	
3.12	Temperature control range	-20 to -30 °C	
3.13	Control & Display	Touch key pad with LED display mounted in the door or Top of the door	
3.14	Tempertaure Regulation	Microprocessor controlled	
3.15	Temperature uniformity	± 2°C across the internal chamber	
3.16	Validation Port	Ports for inserting probes for temperature mapping to be provided	
3.17	Battery back up for panel	To be provided	
3.18	Set point security	To be provided	
3.19	Chart Recorder	To be provided	
3.20	Air circulation	Positive Forced Air circulation	
3.21	Total quantity	7 Nos	
3.22	power required (KW)	To be compatible to standard Indian power supply sockets	

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nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 <b>HBL</b> <small>HLL BIOTECH LIMITED            6th Floor, 10th Cross Street            6th Floor, 10th Cross Street</small>
	Equipment Name	Deep Freezer- Low Temperature	
	Document No.	DS-DPF 02	
	Revision No.	0	
<b>4</b>	<b>Material of Construction</b>		
4.1	Body Construction	Interior	SS 304
4.2		Shelves	Adjustable shelf, SS 304
4.3		Exterior	cGMP compliant
4.4		Inner Door	SS 304 door for each shelf ( not applicable for horizontal deep freezer)
4.5		External Door	cGMP compliant
4.6	Gaskets, seals, o-rings	Food Grade/ nontoxic material	
4.7	Insulation	Polyurethane Foam(PUF)	
4.8	All welds shall be ground finish		
<b>5</b>	<b>Specific Equipment requirement</b>		
5.1	The design of the equipment shall facilitate efficiency and easy cleaning		
5.2	Auto defrost to be provided		
5.3	The equipment shall be compatible for cleaning with all standard disinfectants.		
5.4	Freezer shall be fitted with lockable caster wheels for easy transportation		
5.5	The control shall be microprocessor based with digital display cum controller.		
5.6	Key lock for Parameter change Protection to be provided		
5.7	Temperature to be recorded, monitored and displayed. Temperature probe installed in freezer .		
5.8	Interface port RS 232/RS 485 to transfer data to be provided .		
5.9	Internal clock to be maintained to retrieve data at setpoint interval i.e ; 24 hrs .		
5.10	Positive air circulation by internal fans must be provided to ensure temperature uniformity and recovery.		
5.11	Audio and Visual Alarms for parameters like high temperature, low temperature,door opening shall be provided		
5.12	Door lock should be provided		
5.13	Self closing door (Automatic) shall provided		
5.14	Temperature mapping during installation is required		
5.15	Single compressor shall be provided.		
5.16	Temperature sensor PT 100 / Thermistor should be provided.		
5.17	Equipment shall be compatible for cleaning with all standard disinfectants.		
<b>6</b>	<b>Other requirement</b>		
6.1	Training / demonstration to be provided to users on operation and cleaning to be provided.		
<b>7</b>	<b>Regulatory guidelines / standards</b>		
7.1	CE certification		
<b>8</b>	<b>Safety requirements</b>		
	<b>Following facilities must be provided to protect personnel and equipment:</b>		
8.1	Emergency stop function on accessible area.		
8.2	Noise level Should not be more than 60 decibels.		
8.3	Proper earthing should be provided.		
8.4	No sharp edges/Corners, crevices, in the equipment.		
8.5	Appropriate closure of all parts		

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9	Documents	
	Following documents, but not limited to these, are expected from the vendor as part of supply package in hard copy as well as editable electronic file.	
9.1	IOQ documents.	
9.2	Operation and maintenance manuals shall be provided along with IOQ documents during installation at site.	
9.3	Warranty letter for 1 year from the date of supply.	
9.4	Calibration certificate of critical instrument with respect to the traceable national reference standard instrument and their calibration procedure.	
9.5	List of standard spare parts with ordering information.	
10	Timelines	
10.1	Not Applicable	
11	List of Preferred make	
11.1	Panasonic, JeioTech, Arctiko, Thermo scientific	
	<b>NOTE:</b> Accurate size and technical specification need to be mentioned by the vendor	



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	Revision No.	0			
Table-1: Equipment location					
EQUIPMENT ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
B4-DPF 01	Rabies Vaccine bulk Production	Media Preparation	B4G027	6800 x 4150	2700
B4-DPF 02	Rabies Vaccine bulk Production	Virus Inactivation room	B4G059	5700 x 3350	2700
Q1-DPF 04	Admin QA & QC	Viral sample holding room with deep freezers	Q1S012	3501 x 3550	2400
Q1-DPF 05	Admin QA & QC	Chemical Lab / Bio Chemistry	Q1S022	6250 x 7350	2400
Q1-DPF 11&12	Admin QA & QC	Microbiology Lab	Q1S045	3700 x 4600	2400
P1-DPF 01	Secondary packing	Materials staging for packing - 1	P1S005	4900 x 4080	3000
Table-2: Change Log					
Date	Name	Revision	Section	Change/Comment	
10-02-2016	Sandeep Kumar	00		New document	
Table-3: Annexure (specific equipment details)					
EQUIPMENT ID	Shelf Dimension (W X D mm)	Height between the shelves (mm)	Internal Dimension (W X D X H mm)	External Dimension (W X D X H mm)	
B4-DPF 01	vendor to specify	vendor to specify	vendor to specify	vendor to specify	
B4-DPF 02	vendor to specify	vendor to specify	vendor to specify	vendor to specify	
Q1-DPF 04	vendor to specify	vendor to specify	vendor to specify	vendor to specify	
Q1-DPF 05	vendor to specify	vendor to specify	vendor to specify	vendor to specify	
Q1-DPF 11&12	vendor to specify	vendor to specify	vendor to specify	vendor to specify	
P1-DPF 01	vendor to specify	vendor to specify	vendor to specify	vendor to specify	