

Equipment Specification Data Sheet

Equipment Name: Refrigerator

Document No.: DS-RFR 01




Revision: 04

Project No.: 120310

Project Name: Integrated Vaccines Complex,  
 Chengalpattu

Block Code	Block Name	Identification No.	Capacity (L)	Quantity
B4	Rabies Bulk	B4-RFR 01-02	500	2
B4	Rabies Bulk	B4-RFR 03-04-05	500	3
B4	Rabies Bulk	B4-RFR 06	500	1
G1	Animal House	G1-RFR 01	200	1
G1	Animal House	G1-RFR 02	500	1
G1	Animal House	G1-RFR 03	200	1
Q1	Admin QA & QC	Q1-RFR 01-02	500	2
Q1	Admin QA & QC	Q1-RFR 03	300	1
Q1	Admin QA & QC	Q1-RFR 04	300	1
Q1	Admin QA & QC	Q1-RFR 05	300	1
Q1	Admin QA & QC	Q1-RFR 06	300	1
Q1	Admin QA & QC	Q1-RFR 07	300	1

**NNE Pharmaplan India Limited**

Name	Designation	Signature	Date
<b>Prepared by</b>			
Mr. Manohar M S	Engineer - Process		8/6/15
<b>Checked by</b>			
Ms. Shilpa Rao	Senior Engineer - Process		8/6/15
<b>Approved by</b>			
Mr. Vikas Katial	GM - Projects (SME) & Head COC Vaccines		9/6/15

Equipment Specification Data Sheet

Equipment Name: Refrigerator


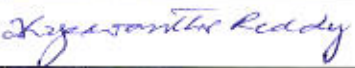







Document No.: DS-RFR 01

Revision: 04

Project No.: 120310

Project Name: Integrated Vaccines Complex,  
Chengalpattu

HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
P. NAVIN KUNAR	DEPUTY MANAGER (VIRAL VACCINE)		15/6/15
K. YASHANTHA REDDY	Deputy Manager		15/6/15
Sanjeev Kumar. R	Managers		12/6/15
Polina Sreenath	Deputy Manager		12/6/15
Approved by			
Dr. Juliet Selvi	Head - Viral Vaccine		20/6/15
Dr. K. A. ARUL ANAND	MANAGER		19/6/15
V. Sivaganesh	Manager		19/6/15
Dr. SURESH BABU	Depy		22/6/15
Authorized by			
Raman. K. Ramachandran	CEO		24/6/15



# Equipment Specification Data Sheet

HLL Biotech Limited, Chennai

nne pharmaplan®

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

Equipment Name Refrigerator

Document No. DS-RFR 01

Revision No. 04



## 1 Process Requirements

1.1 It is used to store materials at 2-8 °C


2	Equipment ID	Minimum Capacity (L) near to standard	Type/Model	Quantity (Nos)
---	--------------	---------------------------------------	------------	----------------


2.1	B4-RFR 01	500	cGMP	1
2.2	B4-RFR 02	500	cGMP	1
2.3	B4-RFR 03	500	cGMP	1
2.4	B4-RFR 04	500	cGMP	1
2.5	B4-RFR 05	500	cGMP	1
2.6	B4-RFR 06	500	cGMP	1 (refer annexure 1)
2.7	G1-RFR 01	200	cGMP	1
2.8	G1-RFR 02	500	cGMP	1
2.9	G1-RFR 03	200	cGMP	1
2.10	Q1-RFR 01	500	-	1
2.11	Q1-RFR 02	500	cGMP	1
2.12	Q1-RFR 03	300	cGMP	1
2.13	Q1-RFR 04	300	cGMP	1
2.14	Q1-RFR 05	300	cGMP	1
2.15	Q1-RFR 06	300	cGMP	1
2.16	Q1-RFR 07	300	-	1

## 3 Technical Specification


3.1	Model	cGMP
3.2	External dimension (W X D X H mm)	vendor to specify (based on the above mentioned capacity)
3.3	Internal dimension (W X D X H mm)	vendor to specify (As per the capacity)
3.4	Shelves (W X D mm)	vendor to specify (As per the capacity)
3.5	Height between the shelves (mm)	vendor to specify
3.6	No. of Shelves	vendor to specify (SS 304 Perforated shelves shall be adjustable)
3.7	Temperature Range	2 °C to 8 °C
3.8	Refrigerant	R 134a
3.9	Temperature precision	± 0.5 °C
3.10	Temperature stability	± 1 °C




Equipment Specification Data Sheet				
HLL Biotech Limited, Chennai				
nne pharmanplan®		INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 <b>HBL</b> HLL BIOTECH LIMITED <small>Subsidiary of HLL Biotech Limited In Government of India Ownership</small>
		Equipment Name	Refrigerator	
		Document No.	DS-RFR 01	
		Revision No.	04	
3.11	Temperature Resolution	± 1 °C		
3.12	Temperature uniformity	± 2 °C		
3.13	Air circulation	Forced air circulation		
3.14	Quantity	16 no.		
3.15	Power requirement	To be compatible to standard Indian Power supply socket.		
4	Material of Construction			
4.1	Body Construction	Interior	SS 304	
4.2		Shelves	Adjustable, Perforated, SS304	
4.3		Exterior	cGMP compliant exterior	
4.4	Gaskets, seals, o-rings	Food Grade/ nontoxic material		
4.5	Insulation	Polyurethane foam(PUF)		
4.6	Door	Stainless steel door		
4.7	All welds shall be ground finish.			
5	Specific Equipment Requirements			
5.1	The design of the equipment should facilitate efficient and easy cleaning			
5.2	The equipment shall be compatible for cleaning with all standards disinfectants			
5.3	Refrigerator shall be fitted with lockable caster wheels for easy transportation.			
5.4	The control shall be microprocessor based with digital display cum controller.			
5.5	Key lock for Parameter change Protection to be provided.			
5.6	Temperature to be recorded, monitored and displayed. Chart recorder to be provided.(PT 100) (for GMP model)			
5.7	Interface port RS 232 to transfer data to be provided.			
5.8	Positive air circulation by internal fans must be provided to ensure temperature uniformity and recovery			
5.9	Audio visual alarms for parameters like high temperature, low temperature shall be provided and if door is open for > 5min.			
5.10	Light on provision during door opening			
5.11	Door lock should be provided.			
5.12	Spring loaded, self-closing door with 90° angle stay open feature should be provided with holder.			
5.13	Validation Ports to be provided for inserting probes for temperature mapping.			
5.14	Temperature mapping during installation is required.			
5.15	Single compressor should be provided.			
5.16	Equipment shall be compatible for cleaning with all standard disinfectant.			
5.17	Design Basis: Refer Annexure 1 for specific design of B4-RFR 06			

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 <b>HBL</b> <small>HLL BIOTECH LIMITED</small> <small>Autonomous of HLL, Chennai 600015</small> <small>in Government of India (Integrated)</small>
	Equipment Name	Refrigerator	
	Document No.	DS-RFR 01	
	Revision No.	04	
<b>6</b>	<b>Other Requirements</b>		
6.1	Training /Demo for the users on operation and cleaning to be provided.		
<b>7</b>	<b>Regulatory Aspects</b>		
7.1	CE certification.		
<b>8</b>	<b>Safety Requirements</b>		
	Following facilities must be provided to protect personnel and equipment:		
8.1	Proper earthing is necessary		
8.2	No sharp edges/Corners in the equipment.		
8.3	Appropriate closure of all parts.		
<b>9</b>	<b>Documents</b>		
	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	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 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		
<b>10</b>	<b>Timelines</b>		
10.1	Not Applicable		
<b>11</b>	<b>List of Preferred makes</b>		
11.1	Thermo scientific, Panasonic, JeioTech, Arctiko, Newtronics		
	<b>NOTE:</b> Accurate size and technical specification need to be mentioned by the vendor		



Equipment Specification Data Sheet					
HLL Biotech Limited, Chennai					
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU			 HLL BIOTECH LIMITED <small>(A Division of HLL Biotech Limited) A Government of India Enterprise</small>	
	Equipment Name	Refrigerator			
	Document No.	DS-RFR 01			
	Revision No.	04			
Table-1: Equipment location					
Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
B4-RFR 01-02	Rabies Bulk	Virus Propagation	B4G046	9250 x 8700	2700
B4-RFR 03-04-05	Rabies Bulk	Purification	B4G057	9350 x 11040	2700
B4-RFR 06	Rabies Bulk	Virus Inactivation	B4G059	5700 x 3350	2700
G1-RFR 01	Animal House	Office	G1G066	5100 x 4000	2700
G1-RFR 02	Animal House	Lab area - Testing	G1G055	4700 x 7300	2700
G1-RFR 03	Animal House	Lab Area (Challenge)	G1G078	4000 x 5000	2700
Q1-RFR 01-02	Admin QA & QC	Retention sample room	Q1S010	4731 x 2580	2400
Q1-RFR 03	Admin QA & QC	Instrumentation Lab	Q1S020	6400 x 3450	2400
Q1-RFR 04	Admin QA & QC	Chemical Lab / Bio Chemistry	Q1S022	6240 x 6805	2400
Q1-RFR 05	Admin QA & QC	Virus Testing Labs	Q1S036	6370 x 3310	2400
Q1-RFR 06	Admin QA & QC	Microbiology Lab	Q1S045	3450 x 5290	2400
Q1-RFR 07	Admin QA & QC	Cell culture area	Q1S069	2700 x 3760	2400

Equipment Specification Data Sheet				
HLL Biotech Limited, Chennai				
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU			 HLL BIOTECH LIMITED <small>(Subsidiary of HBL, Chennai, India) a Government of India Enterprise</small>
	Equipment Name	Refrigerator		
	Document No.	DS-RFR 01		
	Revision No.	04		
Table-2: Change Log				
Date	Name	Revision	Section	Change/Comment
11-07-2014	Manohar	00	-	New document
04-08-2014	Manohar	01	All	Updated as per comments received from HBL dated 04-08-2014
27-10-2014	Manohar	02	All	Updated as per comments received from HBL dated 15-10-2014
06-01-2015	Yogesha M J	03	All	Updated as per comments given by HBL team during meeting dated 06-01-2015 at HBL office
06-05-2015	Manohar	04	All	Updated as per comments received from HBL dated 27-02-2015
Table-3: Annexure (contain specific equipment details)				
EQUIPMENT ID	Door type	Design Basis		
B4-RFR 01-02	TBD			
B4-RFR 03-04-05	TBD			
B4-RFR 06	Double door	Upper chamber upto - 20 °C and Lower compartment ranging from +1°C to +8°C  To hold minimum 4 nos of 20 L Glassbottles after BPL addition, with a chamber for minus 20 deg C for BPL  To store container having 20L (working volume). Glass bottle dimensions: Diameter: 290 mm Height: 290 mm		
G1-RFR 01	Vertical			
G1-RFR 02	Vertical			
G1-RFR 03	Vertical			
Q1-RFR 01-02	Vertical			
Q1-RFR 03	Vertical			
Q1-RFR 04	Vertical			
Q1-RFR 05	Vertical			
Q1-RFR 06	Vertical			
Q1-RFR 07	Vertical			