

Equipment Specification Data Sheet

Equipment Name: Cryogenic storage container(LN2)

Document No.: DS-CSC 01

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex,
Chengalpattu


Block Code	Block Name	Identification No.	Capacity	Quantity
B4	Rabies bulk block	B4-CSC 01-04	-	4
Q1	Admin, QA & QC	Q1-CSC 01-06	-	6


NNE Pharmaplan India Limited


Name	Designation	Signature	Date
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HLL Biotech Limited

Name	Designation	Signature	Date
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Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	Cryogenic storage container(LN2)
	Project #	120310
	Document #	DS-CSC 01
		
1	Process requirements	
1.1	The Cryo storage (LN2) container shall be used to cryopreserve cGMP cell banks for the purpose of manufacturing and testing vaccines.	
2	Equipment ID	
2.1	B4-CSC 01-04	
2.2	Q1-CSC 01-06	
3	Technical Specification for Cryogenic Storage Container	
3.1	Model	cGMP compliant portable model
3.2	System Capability	Minimum 2000 vials
3.3	Storage Capacity	To store 1.2 ml, 2ml and 5 ml cryovials arranged in a secondary SS container
3.4	Syorage Type	Manual loading of vials into the container
3.5	No.s of 2ml vials per canister/rack	Vendor to specify
3.6	Canister/Storage rack capacity	Vendor to specify
3.7	No.of. Canister/ rack	4 (minimum)
3.8	Static evaporation rate	Vendor to specify (with no product load)
3.9	Static Holding time	Minimum 80 days
3.10	Vessel exterior dimensions	Vendor to specify
3.11	Rack Dimension	Size should be suitable to store around 2000 vials of required capacity.
3.12	Quantity	10 nos
3.13	Operational Parameters	Temperature : - 150 °C to - 190 °C
3.14	Storage requirements	a) Provision to ensure that cryovials are stored at vapour phase of nitrogen with physical separation from contact with liquid nitrogen. b) The cryo storage container should be designed to store and retrieve 1.2 ml, 2ml and 5 ml cryovials arranged in a secondary SS container
4	Material of Construction	
4.1	cGMP compliant MOC	
5	Specific Equipment requirment	
5.1	Should have easy access to the stored vials	
5.2	Should have full width top opening, compatible/suitable for storing and retrieving secondary SS containers containing the cryo-vials	
5.3	"Castor wheels"- should be made of heavy duty cGMP compliant material.	
5.4	Should be suitable to be comfortably transported, placed and operated in the specified area	
6	Other requirement	
6.1	Vendor should quote for all critical spares and accessories such as (i.e not limited to) SS square shaped canister racks, storage inventory system such as SS cryo boxes for 2ml cryovials, LN2 transfer hose, cryoprotective gloves and safety goggles which should be provided with each equipment.	
7	Regulatory guidelines/Standards	
7.1	CE certification	

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8	Safety requirements		
8.1	Container opening should be lockable to prevent unauthorized usage		
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	MOC certificates for all the metallic and non metallic parts are required		
9.3	IQ, OQ documentation		
9.4	Surface finish certificates		
9.4	Leak test for LN2 and Vacuum certificates		
9.5	Certificate of conformity to confirm whether the required specification are met (validation document)		
9.6	Test certificates and calibration certificates		
9.7	Certification: CE (European Conformity) certification		
9.8	Warranty for vacuum and equipment should be separately mentioned		
10	Timelines		
10.1	Not Applicable		
11	Preferred list of Makes		
11.1	Thermo Fisher Scientific,MVE,STATE BOURNE,Cryogenics,Marathon		
	NOTE: Accurate size and technical specification need to be mentioned by the vendor		

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	Project #	120310			
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TABLE NO: 1					
Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
B4-CSC 01-04	Rabies Bulk	Cell Lab-2	B4G039	-	-
Q1-CSC 01-02	Admin, QA & QC	Master seed storage-1	Q1S030	-	-
Q1-CSC 03-04	Admin, QA & QC	Master seed storage-2	Q1S031	-	-
Q1-CSC 05	Admin, QA & QC	Cell culture area-1	Q1S071	-	-
Q1-CSC 06	Admin, QA & QC	Cell culture area-2	Q1S072	-	-
Table-2: Change Log					
Date	Name	Revision	Section	Change/Comment	
09-09-2015	Syed Sharique Ahmad	00	-	New document	
Table-3: Annexure					
Not applicable					