

Equipment Name: Cryogenic storage container and Pressurised LN2 Refill Cylinder


Revision: 00


Project Name: Integrated Vaccines Complex,
Chengalpattu


| Block Code | Block Name | Identification No. | Capacity | Quantity |
|------------|-------------------|--------------------|----------|----------|
| B4 | Rabies bulk block | B4-CSS 01 | - | 1 |

| NNE Pharmaplan India Limited | | | |
|--|------------------------------|----------------------|------------|
| Name | Designation | Signature | Date |
| Prepared by | | | |
| Mr. Syed Sharique Ahmad | Process Engineer | <i>for Sandeep</i> | 11-02-2016 |
| Checked by | | | |
| Mr. Yogesha M J | Process Engineer | <i>yogesha-mj</i> | 11-02-2016 |
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| Dr. Harshad Mali | Lead - Process Engineer | <i>for Amrutam</i> | 11/02/2016 |
| | | | |
| HLL Biotech Limited | | | |
| Name | Designation | Signature | Date |
| Reviewed by | | | |
| User department: Rabies billk P. NAVIN KUMAR | DEPUTY MANAGER (NDF) | <i>P. Navin</i> | 16/02/2016 |
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| Authorized by | | | |
| Project Authority <i>K. R.</i> K. R. | C.E.O | <i>K.R.</i> | 19.2.16 |

| Equipment Specification Data Sheet | | |
|---|---|--|
| HLL Biotech Limited, Chennai | | |
| nne pharma plan® | INTEGRATED VACCINES COMPLEX, CHENGALPATTU | |
| | Equipment Name | Cryogenic storage container and Pressurised LN2 Refill Cylinder |
| | Project # | 120310 |
| | Document # | DS-CSS 01 |
|  | | |
| 1 | Process requirements | |
| 1.1 | The Cryo storage container shall be used to cryopreserve cGMP cell banks for the purpose of manufacturing and testing vaccines. The LN2 refill cylinder/ container will be used to automatically refill the cryogenic storage container | |
| 2 | Equipment ID | |
| 2.1 | B4-CSS 01 | |
| 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 | Storage Type | a.) Automatic fill of Liquid Nitrogen b.) 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 | Static evaporation rate | Vendor to specify (with no product load) |
| 3.8 | Static Holding time | Minimum 120 days |
| 3.9 | Vessel exterior dimensions | Vendor to specify |
| 3.10 | Rack Dimension | Size should be suitable to store 2000-6000 vials of required capacity. |
| 3.11 | Quantity | 2 nos of cryostorage container and 2 nos of pressurized LN2 cylinder for automatic refill. |
| 3.12 | Operational Parameters | a.) Working pressure : 30 - 50 psi b.) Temperature : - 150 °C to - 190 °C |
| 3.13 | Additional Requirements | |
| 3.14 | Temperature | a) RTD sensors with an accuracy of +/- 1.0 degree C and a resolution of 0.1 degree C. b) Temperature display in celsius and/or Fahrenheit . c) Hot gas bypass should be provided to vent warm nitrogen gas from the supply line before initiating LN2 fill d) The equipment should be able to store critical data with time for assessing the equipment performance and trouble shooting. e) Menu and settings with customizable security levels using password should be provided f) Temperature (at vapour phase and liquid phase) and liquid nitrogen level digital display g) Temperature and liquid nitrogen low level alarms |
| 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 |

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| 3.15 | Controls | a) Should have automatic liquid nitrogen level control with user defined parameters for low level alarm, low level fill point, high level fill point and high level alarm. The alarms should be in audio and visual modes b) Liquid Nitrogen level measurement should have an accuracy of 15mm and a resolution of 5.0 mm c) The equipment should be able to store critical data with time for assessing the equipment performance and trouble shooting. d) Menu and settings with customizable security levels using password should be provided. e) De-fog system should be present to ensure good visibility f) Automatic monitoring and display of LN2 level g) Control pannel shall be mounted on the top of the unit for convenient assess and easy operation h) Remote alarm system shall be provided. | | |
| 3.16 | LN2 Refill Cyllinder | a) cGMP compliant MOC b) Inline pressure gauge, c) Should be suitable to be comfortably transported, placed and operated in the specified area d) Suitable pressurized Liquid Nitrogen Cylinder of minimum 50 liters capacity to connect to storage vessel for auto-filling e)The wiring and LN2 transfer lines should be completely enclosed | | |
| 4 | Material of Construction | | | |
| 4.1 | cGMP compliant MOC | | | |
| 5 | Specific Equipment requirment | | | |
| 5.3 | LED display should display the level of Liquid Nitrogen and also the high and low level set points. | | | |
| 5.6 | Should have easy access to the stored vials | | | |
| 5.7 | Should have full width top opening, compatible/suitable for storing and retrieving secondary SS containers containing the cryo-vials | | | |
| 5.8 | "Castor wheels"- should be made of heavy duty cGMP compliant material. | | | |
| 5.9 | Should be suitable to be comfortably transported, placed and operated in the specified area | | | |
| 5.10 | The wiring and LN2 transfer lines should be completely enclosed | | | |
| 5.11 | Should be compatible with automatic LN2 filling system with hot gas by-pass | | | |
| 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. | | | |
| 6.2 | The cryostorage container should be integrated with LN2 refill container. | | | |
| 7 | Regulatory guidelines/Standards | | | |
| 7.1 | CE certification | | | |
| 8 | Safety requirements | | | |
| 8.1 | On power failure equipment should come in failsafe condition. | | | |
| 8.2 | Should comply with safety requirements for pressure vessels and with EC Medical Devices Directive 93/42/EC | | | |

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| 8.3 | Container opening should be lockable to prevent unauthorized usage | | |
| 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 | MOC certificates for all the metallic and non metallic parts are required | | |
| 9.2 | IQ, OQ documentation and SAT. | | |
| 9.3 | Surface finish certificates | | |
| 9.4 | Leak test for LN2 and Vacuum certificates | | |
| 9.4 | Certificate of conformity to confirm whether the required specification are met (validation document) | | |
| 9.5 | Test certificates and calibration certificates | | |
| 9.6 | Certification: CE (European Conformity) certification | | |
| 9.7 | 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, Custom BioGenic Systems | | |
| | NOTE: Accurate size and technical specification need to be mentioned by the vendor | | |

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| | Project # | 120310 | | | |
| | Document # | DS-CSS 01 | | | |
| TABLE NO: 1 | | | | | |
| Equipment ID | Block Name | Room Name | Room No | Room dimension in mm | Room height in mm |
| B4-CSS 01 | Rabies Bulk | Cell Lab-2 | B4G039 | - | - |
| | | | | | |
| Table-2: Change Log | | | | | |
| Date | Name | Revision | Section | Change/Comment | |
| 09-09-2015 | Syed Sharique Ahmad | 00 | - | New document | |
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| Table-3: Annexure | | | | | |
| Not applicable | | | | | |

