# User Requirement Specifications
# Pressure vessel

| Block Code | Area | Identification # | Quantity (No.) | Capacity (WV) |
|---|---|---|---|---|
| R1 | Measles and Rubella Bulk block | R1-PRV 01-02 | 2 | 100 L |
| | | R1-PRV 03-04 | 2 | 50 L |
| | | R1-PRV 05-08 | 4 | 20 L |
| | | R1-PRV 09-14 | 6 | 10 L |
| | | R1-PRV 15-20 | 6 | 5 L |

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## 1.0 APPROVAL SIGNATURES

This document is prepared by the Process, Validation and GMP Compliance team of "NNE Pharmaplan India" for the project "Integrated Vaccines Complex, Chengalpattu, Chennai" (**project number:** 120310) of HLL BIOTECH LIMITED (Chennai) under the authority of their Project Manager. Hence, this document before being effective shall be reviewed by HBL user/s and project/ engineering team, approved by team lead of user department & QA and authorized by the appropriate Project authority.

| NNE Pharmaplan India Limited | | | |
|---|---|---|---|
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## 2.0 EQUIPMENT DESCRIPTION

The vessel shall be designed, constructed, built, installed and commissioned to hold solutions and should comply cGMP requirements.
The vessel should be autoclavable

**The equipment should consist of following features in order to run operation smoothly.**
**Table 1**

| S. No. | Description | Purpose | MOC | Remarks |
|---|---|---|---|---|
| 1. | Shell | Cylindrical to hold the product | SS316L | |
| 2. | Top closure | For 5L, 10L, 20L & 50L – Completely detachable Flat lid<br>For 100L : Full openable hinged type lid | SS316L | |
| 3. | Bottom closure | Tori spherical dish with skirt support | SS316L | |

### 2.1 General Description

| S No. | Description | Remarks |
|---|---|---|
| 2.1.1 | **Product transfer:** These autoclavable pressure vessels will be used for the filtration of the media and transfer of other process intermediates | |
| 2.1.2 | For 5 L and 10 L pressure vessel, compact handle for lifting should be provided and a standard SS Skirt at the bottom.<br>For holding 20 L, 50L, 100L vessel, SS 304 trolley mounted on a castor wheels made of polyurethane should be provided. | |
| 2.1.3 | **Surface finish:** All pressure vessels should be internally electro polished with <0.6 Ra finishing and externally should have < 1.2 Ra finishing. | |
| 2.1.4 | Handles shall be collapsible type | |

### 2.2 General Nozzle Schedule

| S No. | Description | Remarks |
|---|---|---|
| 2.2.1 | **Ports required in the top lid:** | |
| | • Air inlet (I.e., provision for vent filter) | |
| | • Media outlet | |
| | • Safety release valve | |
| | • Port for diaphragm pressure gauge | |
| 2.2.2 | The top lid should be completely detachable ,Inlet & Outlet ports(air, product) should be provided with SS 316L hose barb adapter to suit 6 mm to 8 mm ID silicon tubes | |

**Note:** The following points which are there in the IRS (Installation Requirement Specifications) are NOT APPLICABLE for this equipment:

- 4.1.10, 4.1.11, 4.1.13,4.1.17
- **Sec 5.1**
  a. SI.NO 2 and 3 :FDA guidance for industry
  b. SI.NO 5 CE Conformity,SI.NO 7 ANSI/NSF 49-2008, ISO 14664, ISO 8362

c. SI.NO 8 ISO 14664,SI.NO 9 ISO 8362

- Sec 5.6

**Note:**

| | |
|---|---|
| 1. | This Technical Specification is the basis for an inquiry to a vendor and therefore the basis for the vendor's proposal. |
| 2. | The vendor is asked to state in "REMARKS" column with "yes" if the described requirement will be completely fulfilled and with "no" in case the requirement will not or cannot be fulfilled with the proposed equipment. I n case of an deviation a comment must be inserted or enclosed as a separate annexure by referring to the respective URS specification number. |
| 3. | The vendor must clearly comment each item of the Technical Specification. The comments must be in English language. If extra cost for necessary options becomes necessary the item must be clearly stated. |
| 4. | In case that the requirement includes a question or request or information from the vendor, the answer / information should be stated in the "REMARKS" column. |
| 5. | The final version of this document including the vendor's comments will become basis of a potential purchase order or contract. |
| 6. | The Technical Specification serves to define a summary of all vendor's requirements concerning scope of delivery and services. |
| 7. | The vendor is responsible for technically unobjectionable function of the equipment. This TS is not intended to dictate a technical design to the vendor. If agreed upon with the vendor, the vendor can apply his practically proven design. |
| 8. | Special Instruction<br>a. If no comments against any specification shall be considered as "NO" and<br>b. If there is no reply / comments against the complete URS by the vendor then it shall be treated as unresponsive / technically non-compliant and rejected. |
| 9. | All the instruments and controls mentioned in the URS(s) are expected to be standard supply and part of your standard equipment model. In case of any deviation or redundancy or additional scope of supply is noticed, vendor is required to obtain clarification from HBL before submitting the quotes. |
| 10. | The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HBL before submitting the offers. |
| 11. | Refer document Installation Requirement Specification and Specific Instructions with URS; NPI_120310_IRS_S1_01 |
| 12. | Refer Tender document with URS; NPI_120310_EQP_S1_TD 16 |

| Specifications | Remarks |
|---|---|
| **3.0 PROCESS DESCRIPTION** | |
| **3.1 Input & Charging method** | |
| 3.1.1 Components used for the preparation of solution are fed into vessel through a dip tube or by opening the top lid. | |
| 3.1.2 Inlet and outlet ports for air and product should be provided with SS 316L hose barb adapter to suit 6mm ID silicone tube. | |
| **3.2 Brief Process Steps** | |
| 3.2.1 NA | |
| **3.3 Output & Discharging method** | |
| 3.3.1 Transfer of media/Buffer will be done by using sterile compressed air or peristaltic pump. Media outlet should be designed for complete drainability of solutions during operation. | |
| **4.0 PRODUCTIVITY REQUIREMENT** | |
| **4.1 Change Over Time** | |
| NA | |
| **4.2 Other Productivity Requirement** | |
| NA | |
| **5.0 CONTAINMENT** | |
| NA | |
| **6.0 GMP REQUIREMENTS** | |
| **6.1 Process control** | |
| NA | |
| **6.2 Failure mode detection** | |
| NA | |
| **6.3 In – Process control** | |
| NA | |
| **6.4 Level of instrumentation** | |
| NA | |
| **6.5 Batch data display and record printing** | |
| NA | |
| **6.6. GMP requirements (Others)** | |
| 6.6.1 All nozzle connection shall be sanitary type and special attention shall be given in shape and dimension of the nozzle and connection to realize efficient cleaning and sterilization process | |

### 6.7 .Specific requirements

| | |
|---|---|
| In general the equipment has to be designed in a way to get easy and quick access to all necessary maintenance points | |
| 6.7.1. Vessel should be provided with compact handle for lifting and a standard SS Skirt at the bottom. | |
| 6.7.2. Nozzles, adaptors, instrument shall comply with ASME BPE compliant. | |
| 6.7.3. The equipment shall be easily accessible for cleaning | |
| 6.7.4. Gaskets should be made up of food grade/ Silicone/ EPDM. | |
| 6.7.5. Product contact parts should be fabricated with SS 316 L grade and all sanitary joints and connections to be sealed using PTFE/ silicone/ EPDM gasket. | |
| 6.7.6. **Design Parameters:** | |
| 6.7.6.1 Vessel working Pressure- 2.0 kg/ $cm^2$/ F.V<br>6.7.6.2 Vessel design Pressure – 3 kg/ $cm^2$ / FV<br>6.7.6.3 Vessel sterilization Temperature- 121 °C<br>6.7.6.4 Vessel design Temperature- 134 °C | |

### 6.8 .Spares and consumables

| | |
|---|---|
| Vendor should provide all critical spares such as (not limited to) gaskets, 'O'rings required for minimum two years of operation. | |

## 7.0 CONSTRAINTS

### 7.1 Equipment Location and Available Space

| | |
|---|---|
| NA | |

### 7.2.Available Utility

| | |
|---|---|
| NA | |

## 8.0 ABBREVIATION

| Abbreviation | Definition |
|---|---|
| IVC | Integrated Vaccine Complex |
| PRV | Pressure Vessel |
| CIP | Clean In Place |
| SIP | Sterilization In Place |
| cGMP | current Good Manufacturing Practices |
| HBL | HLL Biotech Limited |
| NPI | NNE Pharmaplan India Ltd |
| ISO | International Standards Organization |

## 9.0 REVISION INDEX

| Revision | Date | Reason for Revision |
|---|---|---|
| 00 | 05-04-2016 | First Draft for Client's Review |
| | | |
| | | |

**URS Annexure 1: List of preferred make of components**

| S No. | Description | Preferred Make |
|---|---|---|
| 1. | Pressure gauges | WIKA/Denver/Negele |
| 2. | Safety relief valve | Spirax/Leser/ARI Armaturen |

# User Requirement Specifications
# Media Preparation Vessel

**Media Preparation Vessel**

| Block Code | Area | Identification # | Quantity(Nos) | Capacity L (W.V.) |
|---|---|---|---|---|
| R1 | Measles and Rubella Bulk Block | R1-MPV 01 | 1 | 100 |