# USER REQUIREMENT SPECIFICATIONS

# OF

# QC ISOLATOR

PHARMA DEVILS

**USER REQUIREMENT SPECIFICATIONS**
**FOR**
**QC ISOLATOR**

**List of Contents**

## 1. PREPARATION & APPROVAL SHEET:

**Prepared by**

| Name | Signature | Date | Department |
|---|---|---|---|
| | | | |

**Checked by**

| Name | Signature | Date | Department |
|---|---|---|---|
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**Approved by**

| Name | Signature | Date | Department |
|---|---|---|---|
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## 2. LIST OF GENERAL COMPONENT:

| S.No. | Description |
|---|---|
| 1. | Chamber |
| 2. | Differential pressure monitoring |
| 3. | Blower Motor (FLP) |
| 4. | Frequency inverter |
| 5. | Supply HEPA (Micro fibre glass cartridge) |
| 6 | Blower ( Centrifugal type) |
| 7 | Glove port (PTFE / Circular type) |
| 8 | Gloves / Gauntlets |
| 9 | Control console |
| 10 | RTP (Alpha / Beta Port) |
| 11 | Pneumatic cylinders |
| 12 | Cleaning Gun (SS) |
| 13 | View Panel (AIS) |
| 14 | Emergency Stop Button |
| 15 | Switch Socket |
| 16. | Light System |

## 3. GLOSSARY:

| Abbreviation | Description |
|---|---|
| **URS** | User requirement specifications |
| **DQ** | Design Qualification |
| **IQ** | Installation Qualification |
| **OQ** | Operational Qualification |
| **PQ** | Performance Qualification |
| **PLC** | Programmable Logic Control |
| **Pa** | Pascals |
| **NPL** | National Physical Laboratory |
| **MS** | Microsoft |
| **SFU** | Switch Fuse Unit |
| **RTD** | Resistance Temperature Detector |
| **MOC** | Material of Construction |
| **SS** | Stainless Steel |
| **MS** | Mild Steel |
| **MMI** | Man Machine Interface |
| **MM** | Millimeter |
| **CM** | Centimeter |
| **URS** | User requirement specifications |
| **RTD** | Resistance Temperature Detectors |
| **FG** | Finish Good |
| **API** | Active Pharmaceutical ingredient |
| **HMI** | Human-Machine Interface |
| **VFD** | Variable Frequency Drive |
| **MCB** | Miniature Circuit Breaker |

## 4. TECHNICAL:

| S.No. | Parameters | Required Specifications |
|---|---|---|
| **4.1** | **General** | |
| 4.1.1 | **Description** | Quality Control Isolator is a fixed type single chamber unit with a rotate RTP. |
| 4.1.2 | **Use** | The isolator will design to handle quality control activities for API's, Inprocess and FG. |
| 4.1.3 | **Field Identification** | Shall be installed at Wet Lab |
| **4.2** | **Salient Features** | |
| 4.2.1 | **General** | (i) Unit to be compact with ease of operation.<br>(ii) A closed system with consistent performance.<br>(iii) Ease of maintenance<br>(iv) Easily cleanable with minimum recesses and crevices.<br>(v) All welded joints to be grinded where product may be in contact to smooth finish and lead free.<br>(vi) All gaskets provided to avoid leakages should be amendable for easy removal and re-fixing,<br>(vii) All electrical/pneumatic parts should be pre wired.<br>(viii) Convenient lubrication design<br>(ix) Complete safety interlock design<br>(x) All bolts, nuts on the exterior part of equipment to be preferably with cap head or cap nut.<br>(xi) Parts which are required for cleaning should be provided with quick fixing arrangement |
| 4.2.2 | **Material of Construction** | The isolator chamber is constructed from 3 mm thick, AISI 316 L SS material with 19 mm coving radius. The entire welding is done by TIG welded process, providing a crack free and crevice free smooth inner surface. Service plenum is constructed from 1.6 mm thick AISI 304 SS materials gasketed to the sealed chamber. The differential gauges will be mounted on the service plenum above the chamber. The inner wall of the chamber is polished to Ra <0.6 Micron mirror while the external surface is matt polish (upto Ra <0.70 Micron). |
| 4.2.3 | **Finish** | Visually good |

| S.No. | Parameters | Required Specifications |
|---|---|---|
| 4.2.4 | **Electrical Construction** | Non flameproof / flameproof. |
| **4.3** | **Operational requirements** | |
| 4.3.1 | **Capacity** | Isolator chamber constructed from AISI 316 L SS and dimension is L 1600 x W 600 / 500 x H 800 mm.<br>● Chamber holding platform AISI 304 SS.<br>● Four PTFE Glove ports with gauntlets (sleeve with gloves configuration, size 8") ●Neoprene (Black) and Two 150 mm dia glove ports for passbox (Gauntlets dia 150 mm in Neoprene — Black).<br>● Once through (-ve) pressure air flow.<br>● Supply HEPA and exhaust through HEPA filters (Exhaust with trap disc).<br>● PLC / HMI based non-flame proof control onboard to unit.<br>● WIP provision with PFA (Perfluoroalkoxy) / White gun and silicone tube for chamber with drain to drain vessel. The spray jet from gun<br>is able to reach to every corner of the chamber.<br>● Electrical lighting flush to the inner surface of the chamber.<br>● Toughened glass 10 mm thk. for the isolators slanted viewing panel.<br>● The air handling system shall be on board.<br>● Waste water drain collection vessel 25 Ltrs capacity with visual level indication and detachable valve for transferring when the vessel is full.<br>● Ant vibrating Plate form for Weighing balance<br><br>Out feed Pass box with continuous liner port : Constructed from AISI 316 L SS having size 650 W x 650 / 550 D x 800 H with breathing HEPA<br>filters for keeping the pass box negative to environment but positive to work chamber |
| 4.3.2 | **The Air Handling System** | The isolator air handling system shall be based on a once through basis.<br>An exhaust fan is mounted with in the service plenum powers the system.<br>The inlet supplied with HEPA (hydrophobic - EU-14 Grade) filtered air from<br>room. The exhaust would be via double HEPA filter (In series). The<br>Isolator shall be operated under a negative pressure -40 Pa to –80 Pa, |

| S.No. | Parameters | Required Specifications |
|---|---|---|
| | | providing by 20 ACPH (Minimum) under normal operation. In case of glove failure, air from the room at a velocity of 0.7 m/s through a standard elliptical glove port will be maintained. |
| 4.3.3 | **Air Filtration** | ●Inlet air filter - inlet air pass through a pre-filter (EU-8) followed by 1 No (EU-14) HEPA (hydrophobic) cylindrical / cartridge type filter, push / push style for main chamber.<br>● Exhaust air passes through a set of two exhaust (EU-14) HEPA (hydrophobic) cartridge type filters, in series. The filter inlet is also provided with trap disc which can be fitted for product change over.<br>Entire set of filters are not required to be changed. |
| 4.3.4 | **Service Ports** | All service ports shall be made out of AISI 316 L SS with following connectivity :<br>- TC fitting (20 mm NB) for liquid and 20 mm for gas lines.<br>- 40 mm drain outlet TC type.<br>- 200 mm bag-out port. |
| 4.3.5 | **View Panel** | The view panel is tempered safety glass, 10 mm thick with clamp closing and two SS claded gas spring opening for isolator slanted viewing panel.<br>The SS claded gas spring will be provided for assisting to lift. The front glass view panel gull wing design is open able for complete access. |
| 4.3.6 | **Gloves and Gauntlets** | Sleeve and glove configuration, size 8", docking with cuff design using 'O' ring in EPDM / Neoprene.<br>Four elliptical glove ports 200 x 250 mm, and two 150 mm diameter PTFE MOC. Gloves in Neoprene (Black). |
| 4.4 | **Control Parameter** | The isolator will be having a push button based control systems. The power panel including VFD and MCB's etc. will be placed in a SS panel below the isolator. The operating panel fitted ergonomically on the isolator's |
| 4.4.1 | **Desired Accuracy** | Isolator shall be operated under a negative pressure -40 Pa to –80 Pa, providing by 20 ACPH (Minimum) under normal operation. In case of glove failure, air from the room at a velocity of 0.7 m/s through a standard |

| S.No. | Parameters | Required Specifications |
|---|---|---|
| | | elliptical glove port will be maintained. |
| 4.4.2 | **Control** | Manual & Automatic |
| 4.4.3 | **Data & Security** | Yes with Password |
| 4.4.4 | **User interface with supervisors and operators for the control platform Interface with other Equipment and system** | NA |
| 4.4.5 | **Security level** | 3 Level Password Protection |
| 4.4.6 | **Data collection** | NA |
| 4.5 | **Component Reference details** | YES |
| 4.6 | **Alarm System** | Preferably the sound alarms / beep shall be provided The alarm should be on -<br>(a) If chamber leak test is failed.<br>(b) If the chamber temperature overshoots.<br>(c) If chamber temperature falls below specified level.<br>(d) If chamber temperature falls further below specified level.<br>(e) If chamber pressure is greater than the set value.<br>(f) If Chamber humidity is high. |
| 4.7 | **Power failure / recovery** | In the event of a power failure, The system will stop in a safe mode automatically upon loss of electricity, air or other major utility and will require operator intervention to re-start. |
| 4.8 | **Emergency stop** | The emergency stop mechanism(s) shall be provided. |
| **4.9** | **Utilities** | Supplier to give details and drawings for exact size, location, type, capacity etc. of the utilities required. |
| **4.10** | **Maintenance** | Supplier should provide the following maintenance instructions,<br>Operation and Maintenance manuals along with as built |

| S.No. | Parameters | Required Specifications |
|---|---|---|
| | | drawings<br>Daily checks on machine Cleaning procedures |
| **4.11** | **Inspection and Testing** | Not Applicable |
| **4.12**<br><br><br>4.12.1 | **Commissioning and Documentation**<br><br><br>**Development** | IQ/OQ/PQ to be completed by the supplier along with representatives.<br>The Supplier to demonstrate the Performance of the machine at User site as per agreed terms.<br>The Supplier shall provide a Project Manager for the project to provide a single communication point with the User. |
| **4.13**<br><br><br>4.13.1<br><br>4.13.2 | **Training**<br><br><br>**Start up support**<br><br>**Post start up support** | Supplier to train the respective technical associates on operation, maintenance and cleaning of the equipment wherever applicable.<br><br>Telephone / Fax / E mail ID / Address<br><br>Replacement parts availability list (normal lead times shall be listed)<br>System improvements (supplier shall notify user of any improvements). |
| **4.14** | **Packaging** | Supplier to specify packaging of machine for safe transportation and delivery at the site. |
| **4.15** | **Deviations** | Any deviation from URS shall be highlighted. |
| **4.16** | **Delivery** | As per purchase order. |