/

USER REQUIREMENT SPECIFICATION FOR PRESSURE VESSEL CAPACITY – 50 L, 100 L

LOCATION	**THREE PIECE LINE**
SUPERSEDES URS No.	**NIL**

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 PHARMA DEVILS	USER REQUIREMENT SPECIFICATION FOR PRESSURE VESSEL	URS No.:

1.0 APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- The User Requirements Specification (URS) is provided to aid the user through the critical aspects of Fabrication, Facility for Installation of Required Equipments, Cleaning/Proper Maintenance, cGMP, Safety and Regulatory Requirements
- The URS is then provided to Vendor to submit a Price Quote for procurement of Pressure vessel
- The URS shall help Vendor in understanding the end user requirement in details. This document shall help vendor for developing the Design Specification, which on approval by Site, will become a Contractual Agreement between Vendor and the Site.
- This URS will be recognized as an integral part of the procurement agreement with the vendor. The vendor will abide by the information and conditions set forth by this document as well as the Standard Purchase Terms and Conditions of the Site.

3.0 SCOPE:

- The scope of this document is limited to the User Requirement Specification (URS) of Pressure vessel.
- The URS shall be used as a reference document for considering all aspects of Current Good Pressure Practices (cGMP) and Safety.
- The scope of this protocol is to decide & record User Requirement Specification to meet the criteria of Pressure vessel for intended purpose. Demonstrate that the URS of the Pressure vessel is accordingly to the cGMP, ISPE & cGEP guidelines.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments shall be responsible for the overall compliance of this URS.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Initiation, Approval & Authorization of User Requirement Specification. • Co-ordination with Production, Engineering and Quality Control to prepare User Requirement Specification. • To check the completeness and Technical Accuracy of the URS.
User Department	• Review of User Requirement Specification for compliance with the Product Requirement.
Engineering	• Review of User Requirement Specification. • Assist in preparation of User Requirement Specification.

5.0 GMP/REGULATORY REQUIREMENTS:

- The purpose of Pressure vessel is manufacturing of sterile product as per CGMP guidelines.
- Pressure vessel complies with the “Current Good Pressure Practices”.
- WHO GMP- “Good Pressure for Pharmaceutical Products”.
- Schedule–M - “Good Pressure Practices and Requirements of Premises, Plant & Equipments for Pharmaceuticals Products”.

6.0 EQUIPMENT OVERVIEW:

- Pressure vessel is a equipment used to manufacture of sterile preparation.
- A pressure vessel is usually a large SS vessel having MOC of 316 for contact part and SS 304 for non contact part:

6.1 TECHNICAL SPECIFICATION

S.No.	Name of the Component	MOC	Technical Specification
01.	Model	……	As agreed at the time of finalization of purchase order.
02	Shape	……	Vertical , cylindrical
04	Quantity	……	01 Nos. (50 L)
		……	01 Nos. (100L)
03.	Working capacity	……	50 L. (Water volume)
			100 L. (Water volume)
04	Gross capacity for 30 L.	……	Approx 55 L. (Water volume)
	Gross capacity for 50 L.	……	Approx 110 L. (Water volume)
05	Material of construction	SS316 L.	For contact part
		SS304	For non contact part
06	Shell	SS316 L.	As per manufacturer specifications and as appropriate with the complete system design
07	Bottom	SS316 L.	As per manufacturer specifications and as appropriate with the complete system design
08	Top	SS316L.	As per manufacturer specifications and as appropriate with the complete system design
10	“O”Ring	…….	Silicon food grade
11	Trolley	SS304	With 4 Nos wheel
12	Product inlet	…….	As per manufacturer specifications and as appropriate with the complete system design
13	Outlet nozzle	…….	As per manufacturer specifications and as appropriate with the complete system design
15	Temperature	…….	10°C to 200 °C
16	Pressure	…….	Shall be withstand 3 kg/cm^2
18	Welding	…….	Vessel shall be argon velded.
19	Surface finish of contact parts	…….	Internal electro polish
20	Surface finish of contact parts	…….	Mirror polish
21	Safety features	……	Safety valve shall be provided
22	Compressed air inlet	……	Shall be provided

7.0 OTHER REQUIREMENTS AND CONSTRAINTS:

7.1 FUNCTIONAL REQUIREMENTS:

- Pressure vessel shall comply as per ISPE, cGMP, cGEP Guidelines.

7.2 RELIABILITY AND AVAILABILITY:

- The system shall be available for continuous operation.
- Material of construction used shall be suitable for the intended service so as to withstand the working stress without frequent break down.

7.3 MAINTENANCE:

- The system shall allow for maintenance by trained site personnel with supplier recommended tools and practices.
- The supplier shall replace the parts found to be damaged/ broken during Installation.
- The supplier shall be available at the site when asked in case of major breakdown.
- The supplier shall replace the parts found to be damaged/ broken during installation.

8.0 LIFE CYCLE:

8.1 DEVELOPMENT

- The supplier shall follow cGMP practices in design, development, construction and Installation of the system.

8.2 TESTING

- The system shall be Factory tested by the supplier with approval witness.
- The system shall be commissioned and qualified at site for Installation and Operation by the supplier with approval witness.

8.3 SUPPORT

- Supplier shall provide support for alarm system during Installation, Operation & Performance Qualification.

8.4 DELIVERY

- All parts of the system shall be sourced, delivered and installed by the Supplier.
- The supplier shall provide Functional design specification (MOC) and other qualification documents (DQ) in Soft as well as Hard Copy.
- Operating Manual.

9.0 DOCUMENTS TO BE ATTACHED:

- All MOC Certificates, Manual for Bought out items
- Design Qualification protocol.
- Installation Qualification protocol.
- Operational Qualification protocol.
- Schematic Diagram of machine showing Overall Dimensions.
- Instrument list with manufacturer's calibration certificate.
- Electrical unit Diagram.
- P&ID Diagram / G.A Drawing.
- Operating & Service Manual
- Spare Part List.
- Warranty Certificate of machine

Note: The whole URS is a tentative document. Manufacturer or Vendor will be solely responsible for performance of machine specified in the catalogue or during discussion at the time of finalization of purchase order. Specifications and details mentioned in the DQ, dually signed by Vendor/ Manufacturer and dually signed by Head QA will be treated as final specifications of the machine. The said DQ will be treated as an integral part of purchase order.

10.0 REVIEW COMMENTS:

- The supplier should make/design the Pressure vessel as per technical specification mentioned in the URS.
- For any changes in the design/make of the Pressure vessel, if not as per the URS, prior intimation/approval should be taken by the supplier from the Site.
- All parts should have MOC certificates, test certificates, Calibration certificates for traceability and authenticity.

Approved By
Head - QA
Sign & Date:…….

11.0 ABBREVIATIONS:

URS	:	User Requirement Specification
IB	:	Injection block
PVT.	:	Private
Ltd.	:	Limited
L.	:	Liter
No.	:	Number
Sr.	:	Senior
CQA	:	Corporate quality assurance
cGMP	:	Current Good Pressure Practices
ISPE	:	International Society of Pharmaceutical Engineering
cGEP	:	Current Good Engineering Practices
DQ	:	Design Qualification
MOC	:	Material of Construction
SS	:	Stainless Steel
WHO	:	World Health Organization
PRV	:	Pressure vessel
P & ID	:	Piping and instrumentation design
GA	:	General arrangement
QA	:	Quality Assurance