USER REQUIREMENT SPECIFICATION FOR MANUFACTURING VESSEL CAPACITY - 600L

LOCATION	**AMPOULE LINE**
SUPERSEDES URS No.	**NIL**

CONTENTS

PHARMA DEVILS	USER REQUIREMENT SPECIFICATION FOR MANUFACTURING VESSEL (600 L)	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 Manufacturing 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 the 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 manufacturing vessel for the Site.
- The URS shall be used as a reference document for considering all aspects of Current Good Manufacturing Practices (cGMP) and Safety.
- The scope of this protocol is to decide & record User Requirement Specification to meet the criteria of manufacturing vessel for intended purpose. Demonstrate that the URS of the manufacturing 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.

5.0 GMP/REGULATORY REQUIREMENTS:

The purpose of Pressure vessel is to manufacture the sterile preparation.

- WHO GMP- "Good Manufacturing for Pharmaceutical Products".
- Pressure vessel complies with the "Current Good Manufacturing Practices".
- Schedule–M - "Good Manufacturing Practices and Requirements of Premises, Plant & Equipments for Pharmaceuticals Products".

6.0 EQUIPMENT OVERVIEW:

- Manufacturing vessel shall be able to perform heat/cool, mix and stir liquid in liquid and soluble solids in liquid by bottom stirrer with following features:
  - Working Volume : 600, Liters
  - Provision for SIP & CIP process.
  - Inbuilt temperature sensor for temperature monitoring.
  - In built lamp for visibility of bulk solution.
  - Port for Nitrogen & Compressed Air.
  - Nitrogen Purging Filter Should be provided with housing.
  - Load cell for measuring the volume.
  - Sampling point for bulk sampling.
  - SS 304 Jacket is provided to heat and cool product by using steam and cooling

6.1 TECHNICAL SPECIFICATION

S.No.	Name of the Component	MOC	Technical Specification
1.	Model	……	The equipment should be a cGMP model, in term of surface finish, absence of sharp corners, cleanability, assembling and dismantling of components and control system for its intended use. Ease of Cleanability. CIP (Clean in Place) to simplify the cleaning operation and SIP (Sterilization in Place) to simplify the Sterilization operation..
2.	Shape & type	……	Vertical , Cylindrical , Jacketed manufacturing vessel with leg supported
3.	Top dished end	……	Torispherical
4.	Bottom dished end	……	Torispherical
5.	Quantity	……	600 L. (01 nos.)
6.	Working capacity	……	600 L. (Water volume)
7.	Gross capacity for 600 LTR	……	Approx 600 L. (Water volume)
8.	Material of construction	SS316L	For contact part
		SS304	For non contact part
9.	Jacket Connection	---	• Steam Inlet • Steam Condensate • Jacket Drain • Cooling Inlet

S.No.	Name of the Component	MOC	Technical Specification
			• Cooling outlet Air vent/Pressure gauge/Safety Valve should be provided on jacket shell.
10.	Gasket	Silicon	Equipment requirement
11.	Shell thickness	…….	As per your specifications and as appropriate with the complete system design
12.	Bottom thickness	…….	As per your specifications and as appropriate with the complete system design
12.	Top thickness	…….	As per your specifications and as appropriate with the complete system design
13.	Surface finish of contact parts	…….	Internal electro polish Ra ≤ 0.5µm
14.	Surface finish of noncontact parts	…….	Mechanical Polish Ra ≤ 0.9µm
15.	Hydro pressure	…….	Shell -5.2 Bar (g)
			Jacket -5.2 Bar (g)
17.	Temperature sensor with transmitter	…….	Approx range -10 to 200 ° C
18.	Trolley	SS304	As per your specifications and as appropriate with the complete system design
19.	Product inlet	…….	As per your specifications and as appropriate with the complete system design
20.	Outlet nozzle	…….	As per your specifications and as appropriate with the complete system design
21.	Temperature	…….	10°C to 200 °C
22.	Pressure	…….	Shall be withstand 3 kg/cm^2
23.	Impeller	…….	Magnetic stirrer, Backward curved., high shear RPM –Approx 50-500
24.	Welding	…….	Vessel shall be argon welded.
25.	Safety features	…….	Alarm shall be provided
			Safety valve shall be provided
			Noise level below 85 db.
26.	Earthing	…….	Whole body earthing
27.	Compressed air inlet	…….	For compressed air
28.	Insulation	…….	Bounded on external surface of jacket shell and Bottom
29.	Magnetic stirrer	…….	Bottom entry magnetic stirrer

S.No.	Name of the Component	MOC	Technical Specification
30.	High shear mixer	…….	Shall be provided
31.	SS panel	…….	SS304 floor mounted control cum operating panel
32.	Spray ball	…….	Self rotating , 360 ° detachable
33.	Compound gauge	…….	As per your specifications and as appropriate with the complete system design
34.	Sterile safety valve	SS 316	As per your specifications and as appropriate with the complete system design
35.	Vent filter	…….	0.2 Micron Shall be provided
36.	Diaphragm valves	…….	Manual operated Shall be provided for spray ball isolation ,vent filter isolation, N_2 inlet ,WFI inlet
37.	Load cell	…….	± 0.1% accuracy
39.	Flexible hose	…….	Shall be provided for Utility
40.	Sampling Valve arrangement	…….	Shall be provided for sampling
41.	CIP/SIP connection	…….	Detachable arrangement of spray ball And valves
42.	Temperature sensor	Pt-100	Approximately range : 0-200 ° C
43.	Drain port	…….	Drain port shall be provided
44.	Printer	…….	Online DOT matrix printer shall be provided

7.0 OTHER REQUIREMENTS AND CONSTRAINTS:

❖ FUNCTIONAL REQUIREMENTS:

- Manufacturing vessel shall comply as per, cGMP,
- Functional parameters such as Temperature, and, Pressure should be designed as per the requirement as of client.

❖ RELIABILITY AND AVAILABILITY:

- The equipment shall be available for continuous use.
- The material of construction used shall be suitable for the intended service so as to withstand the working stress without any damage.

❖ MAINTENANCE:

- The equipment shall allow for maintenance by trained site personnel with supplier recommended tools and practices.
- Recommended spare parts list shall be provided.
- 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.

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 manufacturing vessel as per technical specification mentioned in the URS.
- For any changes in the design/make of the manufacturing 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.

11.0 ABBREVIATIONS:

URS	:	User Requirement Specification
cGMP	:	Current Good Manufacturing Practices
ISPE	:	International Society of Pharmaceutical Engineering
cGEP	:	Current Good Engineering Practices
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
MOC	:	Material of Construction
SS	:	Stainless Steel
WHO	:	World Health Organization
mm	:	Millimeter
MFT	:	Manufacturing vessel
CIP	:	Cleaning in Place
SIP	:	Sterilization in Place
Db	:	Decibel
WFI	:	Water for Injection
N_2	:	Nitrogen
GA	:	General arrangement
QA	:	Quality Assurance