USER REQUIREMENT SPECIFICATION FOR MANUFACTURING VESSEL CAPACITY – 1300 L

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

CONTENTS

PHARMA DEVILS	USER REQUIREMENT SPECIFICATION FOR MANUFACTURING 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 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.
Engineering	• Review of User Requirement Specification. • Assist in preparation of User Requirement Specification.

5.0 GMP/REGULATORY REQUIREMENTS:

The Purpose of procuring Manufacturing vessel is to hold product after filtration.

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

6.0 EQUIPMENT OVERVIEW:

- Working Volume :1300 Liters with magnetic stirrer
- Provision for SIP & CIP process.
- Inbuilt temperature sensor for temperature monitoring.
- 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 water.

6.1 TECHNICAL SPECIFICATION

S.No.	Name of the Component	MOC	Technical Specification
01.	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.
02	Shape	…….	Vertical, cylindrical, jacketed Manufacturing vessel & insulated with leg supported.
03	Top dished end	…….	Torispherical
04	Bottom dished end	…….	Torispherical
05	Quantity	…….	1300 L. (01NOS.)
06	Working capacity	…….	1300 L. (Water volume)
08	Material of construction	SS316L	For contact part
		SS304	For non contact part
09	Gasket	……..	Silicon
10	Shell Thickness	SS316L	As per your specifications and as appropriate with the complete system design
11	Bottom Thickness	SS316L	As per your specifications and as appropriate with the complete system design
12	Top Thickness	SS316L	As per your specifications and as appropriate with the complete system design
13	Trolley	SS304	With 4 Nos. wheel
14	Hydro pressure		Shell : 5.2 Bar (g)
			Jacket : 5.2 Bar (g)
15	Product inlet	…….	As per your specifications and as appropriate with the complete system design
16	Outlet nozzle	…….	As per your specifications and as appropriate with the complete system design
17	Pressure	…….	Shall be withstand 3 kg/cm^2
18	Impeller	…….	Backward curved, impeller , RPM –Approx 50-500
19	Welding	…….	Vessel shall be argon welded.
20	Surface finish of contact parts	…….	Internal electro polish Ra ≤ 0.5µm
21	Surface finish of noncontact parts	…….	Mechanical Polish Ra ≤ 0.9µm

S.No.	Name of the Component	MOC	Technical Specification
22	Safety features	…….	Safety valve shall be provided
		…….	Noise level below 85 db.
		…….	All moving parts cover should be provided for
		…….	Whole body earthing
23	Jacket Connection	…….	Steam Inlet Steam Condensate Jacket Drain Cooling Inlet Cooling outlet
24	Compressed/N2 air inlet	…….	As per your specification
25	Insulation	…….	As per your specification
26	Magnetic stirrer	…….	As per your specification
27	High shear mixer	…….	Shall be provided
28	Spray ball	…….	Self rotating ,360°, detachable
29	Compound Gauge	…….	As per your specifications and as appropriate with the complete system design.
30	Sterile Safety Valve	…….	As per your specification
31	Vent Filter	…….	0.2 Micron Shall be provided
32	Diaphragm Valves	…….	Manual operated Shall be provided for spray ball isolation ,vent filter isolation, N_2 inlet ,WFI inlet
33	Load Cell	…….	Approx 1000 kg.with ± 0.1% accuracy
34	Flexible Hose	…….	Shall be provided for Utility
35	Sampling Valve arrangement	…….	Manual operated zero dead log valve
36	CIP/SIP Connection	…….	Detachable arrangement of spray ball and valves
37	Temperature sensor	Pt-100	Range Approximately range (-20-200°C)
38	Drain port	…….	Drain Port Shall Be Provided
39	SS Control Panel	…….	SS304 floor mounted control cum operating panel
40	Printer	…….	Online DOT matrix printer shall be provided

7.0 OTHER REQUIREMENTS AND CONSTRAINTS:

7.1 FUNCTIONAL REQUIREMENTS:

- Manufacturing vessel shall comply as per ISPE, cGMP, cGEP Guidelines.
- Functional parameter such as temperature and pressure should be designed as per requirement as of client

7.2 RELIABILITY AND AVAILABILITY:

- The system shall be available for continuous operation.
- The electrical and other 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.
- 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.

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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 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
- Test Certificate of SS Materials

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.

Approved By:……
Head - QA
Sign & Date

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
WG	:	Water Gauge
Hz	:	Hertz
V	:	Volt
Al	:	Aluminum
HLV	:	Manufacturing vessel
CIP	:	Cleaning in Place
SIP	:	Sterilization in Place
RPM	:	Rotation per Minute
Db	:	Decibel
WFI	:	Water for Injection
N_2	:	Nitrogen
P & ID	:	Piping and instrumentation design
GA	:	General arrangement
GMP	:	Good Manufacturing Practices
Ra	:	Roughness average
µ	:	micron