USER REQUIREMENT SPECIFICATION FOR CLEAN IN PLACE/STERILIZATION IN PLACE MODULE

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

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PHARMA DEVILS	USER REQUIREMENT SPECIFICATION FOR CLEAN IN PLACE/STERILIZATION IN PLACE	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 :

- This URS has been initiated by …….. and pertains to procurement of Combined CIP/SIP Module..
- The User Requirements Specification (URS) is provided to aid the user through the critical aspects of Fabrication, Facility for Installation of Required Instruments, Cleaning/Proper Maintenance, cGMP, Safety and Regulatory Requirements necessary to construct and fabricate a functional Combined CIP / SIP Module that meets the user's needs in the most cost-effective method possible.
- The URS is then provided to Vendor to submit a Price Quote for procurement of Combined CIP / SIP Module.
- 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 ……. will become a Contractual Agreement between Vendor and ……
- This URS Shall 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 ……...

3.0 SCOPE:

- The scope of this document is limited to the User Requirement Specification (URS) of Combined CIP/SIP Module of ……...
- The URS shall be used as a reference document for Design Qualification considering all aspects of Current Good Manufacturing Practices (cGMP) and Safety.

4.0 RESPONSIBILITY:

The Team, 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 and Approval of User Requirement Specification. • Co-ordination with User Department 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 Combined CIP/SIP Module is to perform Cleaning as well as Sterilization in Place of vessels in the injection Block.

- Combined CIP/SIP Module should complies with the “Current Good Manufacturing Practices”.
- Schedule–M “Good Laboratory Practices and Requirements of Premises, Plant & Equipments for Pharmaceuticals Products”.

6.0 SYSTEM OVERVIEW:

- CIP / SIP Module shall be able to perform Clean in place of vessels with following wash cycles:
  - Hot Purified Water once through Pre wash cycle-Fixed.
  - Purified Water recirculated wash cycle-Optional.
  - Purified Water recirculated wash cycle-Optional.
  - WFI once through rinse cycle- Fixed.
- CIP / SIP Module shall be able to perform sterilization in place through pure steam at minimum temperature of 121.4^{o}C in 30 min and final purging through Sterile Air.
- **Capacity:** Capable to Clean and sterilize in place vessels**.**
- Both Process Clean in Place and Sterilization in Place Should be able to perform simultaneously for different equipments.

6.1 TECHNICAL SPECIFICATION:

S.No.	Name of the Component	MOC	Technical Specification
1.	Model	……	As agreed at the time of finalization of purchase order.
2.	Shape Of CIP tank	……	Vertical , Cylindrical , Leg supported with Castor wheel
3.	Top dished end	……	Torispherical
4.	Bottom dished end	……	Torispherical
5.	Working Capacity	……	250 L. (01 NO.)
6.	Material of construction	SS316L	For contact part
		SS304	For non contact part
7.	Shell Thickness	SS316L	As per your specifications and as appropriate with the complete system design.
8.	Bottom Thickness	SS316L	As per your specifications and as appropriate with the complete system design.
9.	Surface finish of contact parts	…….	Internal electro polish Ra ≤ 0.5µm
10.	Surface finish of noncontact parts	…….	Mechanical Polish Ra ≤ 0.9µm
11.	Safety features	…….	Alarm shall be provided
		……	Safety valve shall be provided
12.	Insulation	…….	Cladding on shell & bottom.
Requirement For CIP			
13	Spray ball	…….	Self rotating,360° ,detachable

S.No.	Name of the Component	MOC	Technical Specification
14	Safety valve	…….	As per your specifications and as appropriate with the complete system design.
15	Vent filter	…….	Size : 02 micron plain 5” long
16	Level sensor	…….	For level measurement
17	Pneumatic operated diaphragm valves	…….	As per your specifications and as appropriate with the complete system design
18	Pneumatic ball valve	…….	Shall be provided
19	Auto steam trap unit	…….	As per your specifications and as appropriate with the complete system design.
20	Diaphragm valves	…….	Auto Diaphragm Shall be provided
21	Pressure gauge For jacket	…….	Approx 0-10 bar
22	Safety Valve for Jacket	…….	Qty. 01 Nos.
23	Air filter	…….	Make : Pall Qty. 01 No. 0.2 µ
24	CIP Recirculation pump	…….	As per your specifications and as appropriate with the complete system design
25	Conductivity sensor with analyzer	…….	Qty. 01 No.
26	Variable frequency drive for pump	…….	As per your specifications and as appropriate with the complete system design
27	Interconnection piping	…….	As per your specifications and as appropriate with the complete system design
28	Level switch	…….	Qty.01 Nos. For pump dry run protection
29	Flexible hose	…….	Shall be provided as per system requirement
30	Compound gauge	…….	As per your specifications and as appropriate with the complete system design.
31	Trolley- SS	SS304	As per cGMP Requirements
32	Coated Nylon Swivel Castor wheels	SS304	
33	Trolley Mounted Electrical Control Panel	SS304	
34	Condensate pipe and fitting	SS316L	
35	Steam Valve	SS316L	

S.No.	Name of the Component	MOC	Technical Specification
36	Compressed Air Valve	SS316L	
Req37uirement For SIP			
38	Temperature sensor with transmitter	Pt-100	Approximately range : Approx 0-200 ° c
39	Pressure sensor with transmitter	…….	As per your specifications and as appropriate with the complete system design
40	Angel control valve	…….	As per your specifications and as appropriate with the complete system design
41	3 way control valve	…….	As per your specifications and as appropriate with the complete system design.
42	Sterile steam trap unit	SS 316	As per your specifications and as appropriate with the complete system design.
43	Sterile safety valve	SS 316	As per your specifications and as appropriate with the complete system design.
44	Air filter	…….	0.2 µ
45	Pressure gauge	…….	Approx 0-10 Bar (g)
46	Interconnection piping	…….	As per your specifications and as appropriate with the complete system design
47	Printer	…….	DOT Matrix online printer

7.0 OTHER REQUIREMENTS AND CONSTRAINTS:

➢ FUNCTIONAL REQUIREMENTS:

- CIP/SIP Module shall comply as per ISPE, cGMP, cGEP Guidelines.

➢ 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.

➢ 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.

8.0 LIFE CYCLE:

8.1 DEVELOPMENT:

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

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 Preventive maintenance plan development, Operation & cleaning procedure for combined CIP / SIP Module, Assembly and Operator training.
- Supplier shall provide Safety Manuals during Installation, Operation & Calibration at the site.

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 & Calibration Certificates) and Operation Manual in Soft as well as Hard Copy.

9.0 DOCUMENTS TO BE PROVIDED:

- 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, duly signed by Vendor/ Manufacturer and duly 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:

- For any changes in the design/make of the combined CIP / SIP Module if not as per the URS, prior intimation/approval should be taken by the supplier from ……..
- 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
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
MOC	:	Material of Construction
cGMP	:	Current Good Manufacturing Practices
HP	:	Horse power
CIP/SIP	:	Clean In Place/Sterilization In Place
S.S	:	Stainless Steel
ISPE	:	International Society of Pharmaceutical Engineering
cGEP	:	Current Good Engineering Practices
Qty.	:	Quantity
P & ID	:	Piping and instrumentation design
GA	:	General arrangement
QA	:	Quality Assurance
NO.	:	Number
GMP	:	Good Manufacturing Practices
Sr.	:	Senior
Ra	:	Rough analysis
µ	:	micron
N2	:	Nitrogen
RPM	:	Rotation per Minute
Db	:	Decibel
WFI	:	Water for Injection
Hz	:	Hertz
V	:	Volt
Al	:	Aluminum