



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

**USER REQUIREMENT SPECIFICATION
FOR
PURE STEAM GENERATION &
DISTRIBUTION SYSTEM**

URS No.:

REVISION No.: 00

EFFECTIVE DATE:

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**USER REQUIREMENT
SPECIFICATION
FOR
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LOCATION	
SUPERSEDE URS No.	NIL



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1.0 PREPARATION, REVIEW, APPROVAL AND AUTHORIZATION:

PREPARED 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)			



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2.0 OBJECTIVE:

- This URS has been initiated by, and pertains to procurement of **Pure Steam Generation & Distribution System.**
- 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 necessary to construct and fabricate a functional **Pure Steam Generation & Distribution System for LVP Block** 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 **Pure Steam Generation & Distribution System.**
- 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, will become a contractual agreement between vendor.
- 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.

3.0 SCOPE:

- The scope of this document is limited to the User Requirement Specification (URS) of **Pure Steam Generation & Distribution System.**
- 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	<ul style="list-style-type: none">• Initiation and Approval of User Requirement Specification.• Co-ordination with Production and Engineering to prepare User Requirement Specification.• To check the completeness and Technical Accuracy of the URS.
User Department	<ul style="list-style-type: none">• Review of User Requirement Specification for compliance with the Product Requirement.

5.0 GMP/REGULATORY REQUIREMENTS:

- The Purpose of procuring **Pure Steam Generation & Distribution System** is to provide Pure Steam.
- **Pure Steam Generation & Distribution System** complies with the “Current Good Manufacturing Practices”.
- WHO GMP “Good Manufacturing Practices for Pharmaceutical Products”.
- Schedule–M “Good Manufacturing Practices and Requirements of Premises, Plant & Equipments for Pharmaceuticals Products”.

6.0 SYSTEM OVERVIEW:

- The **Pure Steam Generation & Distribution System** and its associated equipment are designed to process Pure Steam in accordance with cGMP principles.
- The major components of the machine includes:
 1. **Outer Column Shell**
 2. **Feed water & Cooling water cooler**
 3. **Heat Exchanger.**
 4. **Distribution System.**



7.0 TECHNICAL SPECIFICATION:

S.No.	Name of the Component	MOC	Technical Specification
PURE STEAM GENERATION SYSTEM:			
1.	Outer Column Shell	SS 316L	As per your specifications and as appropriate with the complete system design.
2.	Heat Exchanger (Inner column)	SS 316L	As per your specifications and as appropriate with the complete system design.
3.	Feed water & Cooling water cooler (Double Tube sheet)	SS316L	As per your specifications and as appropriate with the complete system design.
4.	Capacity	-	500 kg/cm ² LPH with online conductivity meter, flow meter & auto-dumping valve facility.
PURE STEAM DISTRIBUTION SYSTEM:			
5.	PSG (Capacity 500 kg/hr)	SS 316L	As per your specifications and as appropriate with the complete system design
6.	Pressure	NMT 6.0 kg/cm ²	As per your specifications and as appropriate with the complete system design
7.	Tubes for distribution:	SS 316L	As per your specifications and as appropriate with the complete system design
8.	Internal Finish (Electro-polish)	<0.5 Ra, Electro-polish	As per your specifications and as appropriate with the complete system design
9.	Welding	Orbital TIG Welding	As per your specifications and as appropriate with the complete system design
10.	Tri-clover clamps With Silicon gaskets	-	As per Requirements
11.	Actuated Diaphragm Valves	Contact Parts SS 316L	As per Requirements
12.	Manual Diaphragm Valves	Contact Parts SS 316L	As per Requirements
13.	Diaphragm in Valves	-	PTFE Backed EPM Rubber



8.0 OTHER REQUIREMENTS AND CONSTRAINTS:

➤ **FUNCTIONAL REQUIREMENTS:**

- **Pure Steam Generation & Distribution System** shall comply as per ISPE, cGMP, cGEP guidelines.

➤ **RELIABILITY AND AVAILABILITY:**

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



9.0 LIFE CYCLE:

9.1 DEVELOPMENT:

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

9.2 TESTING:

9.2.1 The system shall be Factory tested by the supplier with approval witness.

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

9.3 SUPPORT:

9.3.1 Supplier shall provide support for Preventive maintenance plan development, cleaning (In-place/out of place) procedure for **Pure Steam Generation & Distribution System** and Operator training.

9.3.2 Supplier shall provide Safety Manuals during Installation, Operation & Performance Qualification.

9.4 DELIVERY:

9.4.1 All parts of the system shall be sourced, delivered and installed by the Supplier.

9.4.2 The supplier shall provide Functional design specification (MOC & Calibration Certificates) and other qualification documents (DQ, IQ, OQ & Operation Manual) in Soft as well as Hard Copy.

10.0 DOCUMENTS TO BE PROVIDED:

- All MOC Certificate, Manuals for bought out items.
- Design Qualification.
- Installation Qualification.
- Operational Qualification.
- Schematic Diagram of Machine Showing overall dimension.
- Instrument list with manufacturer's calibration Certificate.
- Electrical Unit Diagram.
- P & I Diagram.
- Operating & Service Manual.
- Spare Part List.

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.



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11.0 REVIEW COMMENTS:

- 11.1.1** The supplier should make/design the **Pure Steam Generation & Distribution System** as per technical specification mentioned in the URS.
- 11.1.2** For any changes in the design/make of the **Pure Steam Generation & Distribution System** if not as per the URS, prior intimation/approval should be taken by the supplier from
- 11.1.3** All parts should have MOC certificates, test certificates, Calibration certificates for traceability and authenticity.

Reviewed By: _____
(Head QA)
(Sign/Date)



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12.0 ABBREVIATIONS:

URS	:	User Requirement Specification
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
MOC	:	Material of Construction
cGMP	:	Current Good Manufacturing Practices
cGEP	:	Current Good Engineering Practices
PSG	:	Pure Steam Generator
SS	:	Stainless Steel