



PHARMA DEVILS

**USER REQUIREMENT SPECIFICATION
FOR
AMPOULE VERTICAL ULTRASONIC WASHING
MACHINE**

URS No.:

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FOR
AMPOULE VERTICAL ULTRASONIC
WASHING MACHINE**

LOCATION	Ampoule line
SUPERSEDES URS No.	NIL



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1.0 APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (USER DEPARTMENT)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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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 Instruments, Cleaning / Proper Maintenance, cGMP, Safety and Regulatory Requirements necessary to construct and fabricate a functional Ampoule filling Machine 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 Ampoule Vertical Ultrasonic Washing Machine.
- 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 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 Site.

3.0 SCOPE:

- The scope of this document is limited to the User Requirement Specification (URS) of Ampoule Vertical Ultrasonic Washing Machine of the Site.
- The URS shall be used as a reference document for Design Qualification considering all aspects of Current Good Manufacturing Practices (cGMP) and Safety.



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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 User Department 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.
Engineering	<ul style="list-style-type: none">• Review of User Requirement Specification.• Assist in preparation of User Requirement Specification.



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5.0 GMP/REGULATORY REQUIREMENTS:

The Purpose of procuring Ampoule Vertical Ultrasonic Washing Machine is to Washing of various sizes of glass ampoule at specified quantity of Water, speed and time. Perform washing of ampoule as well as drying by air of Ampoules.

- Ampoule Vertical Ultrasonic Washing Machine 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:

Ampoule Vertical Ultrasonic Washing Machine consists of the following parts, such as infeed conveyor belt, ultrasonic cleaning part, scroll lifting part, water & rinsing part, out feed part and water & air circulation system.



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6.1 TECHNICAL SPECIFICATION

S.No.	Name of the Component	MOC	Technical Specification
1.0	Equipment Name	-----	Ampoule Vertical Ultrasonic Washing Machine
2.0	Modal /Type	-----	Should be in compliance with cGMP.
3.0	Overall Size of the Machine	-----	As per your specification
4.0	Top & bottom frame	SS 316	As per cGMP Requirement
5.0	Capacity	-----	1 to 5 ml ampoules
6.0	Quantity	-----	01
7.0	Machine specification	-----	As per your specification & cGMP Requirement
8.0	Washing Specification		Recycle Water → Compressed Air → → Purified Water → Compressed Air → WFI → Compressed Air
9.0	Filter Housing		Consisting Filter Housing in Filter of Recycle Water, Purified Water, WFI & Compressed Air
10.0	Ultrasonic Generator		Ultrasonic Vibrator for coarse cleaning, external precision cleaning, internal precision cleaning, bottle outfeed
11.0	Function requirement specification	-----	Machine should be operated by manual and auto mode on PLC Machine should be PLC based control with back Lit alphanumeric display HMI with data logging and printing facility. Should be able to eliminate the particle from inner and outer surface of ampoules. Ampoules should be free of any particle from both inner and outer side of ampoules. Control panel should be made in SS304 Operating the tunnel through PLC should be accessed through password and change of values in set parameter should access through different password level.



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S.No.	Name of the Component	MOC	Technical Specification
			<p>Four Magnehelic Pressure gauges should be provided each for pressure water & Compressed Air.</p> <p>All fault indication should be displayed in alarm list and should have Visual display on control panel or in PLC.</p>
12.0	Operational interlocking facility	-----	<ul style="list-style-type: none"> Emergency stop button should be provided in the control panel. Conveyor stops – Maximum Ampoule accumulation at tunnel infeed – washing machine stop. Conveyor starts – Minimum ampoule accumulation at tunnel infeed – washing machine start.
13.0	Machine body	SS316L	Contact Parts
		SS304	Non Contacts
14.0	Motor	-----	As per your specification & suits for equipment design
	Vibrator Controllers	-----	As per your specification & suits for equipment design
15.0	Emergency Switch	-----	Push Button
16.0	Safety Features	-----	<ul style="list-style-type: none"> Separate electrical control panel with double earthing provision Emergency OFF switch. All electrical wires should be given appropriately number and identified and covered with guard. All moving parts should be properly covered. <p>Control panel should be provided with high/low voltage protection facility.</p>



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S.No.	Name of the Component	MOC	Technical Specification
17.0	Indicating lamp	-----	As per your specification
18.0	Safety Guard	-----	As per your specification
19.0	Earthing	-----	Whole body Earthing
20.0	Special feature	-----	As per Purchase order.

7.0 OTHER REQUIREMENTS AND CONSTRAINTS:

7.1 FUNCTIONAL REQUIREMENTS:

- Ampoule Vertical Ultrasonic Washing Machine shall comply as per ISPE, cGMP, cGEP Guidelines.

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 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 Ampoule Vertical Ultrasonic Washing Machine, 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.



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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.
- 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.



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10.0 REVIEW COMMENTS:

- For any changes in the design/make of the Ampoule Vertical Ultrasonic Washing Machine 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)



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11.0 ABBREVIATIONS:

cGEP	:	Current Good Engineering Practices
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
GA	:	General arrangement
GMP	:	Good Manufacturing Practices
IQ	:	Installation Qualification
ISPE	:	International Society of Pharmaceutical Engineering
LTD.	:	Limited
Min	:	Minute
MOC	:	Material of Construction
NO.	:	Number
OQ	:	Operational Qualification
QA	:	Quality Assurance
Sr.	:	Senior
SS	:	Stainless steel
URS	:	User Requirement Specification
UWM	:	Ampoule Vertical Ultrasonic Washing Machine