



PHARMA DEVILS

**USER REQUIREMENT SPECIFICATION
FOR
AUTOMATIC EXTERNAL AMPOULES WASHING,
DRYING & SELF ADHESIVE LABELING MACHINE**

URS No.:

**USER REQUIREMENT
SPECIFICATION
FOR
AUTOMATIC EXTERNAL AMPOULES
WASHING, DRYING & SELF
ADHESIVE LABELING 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 Equipments, Cleaning/Proper Maintenance, cGMP, Safety and Regulatory Requirements
- The URS is then provided to Vendor to submit a Price Quote for procurement of Automatic External Ampoules Washing Drying & self Adhesive Labeling 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 will become a Contractual Agreement between Vendor and 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 Automatic External Ampoules Washing Drying & self Adhesive Labeling machine.
- 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.



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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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Review of User Requirement Specification for compliance with the Product Requirement.



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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:

- Infeed tray
- Star wheel assembly
- Tank assembly
- Air knife assembly.
- Out feed feed worm assembly
- label dispensing device
- Pressing device
- Etc.



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6.1 TECHNICAL SPECIFICATION:

Name of Components	Acceptance Criteria
Basic Machine	
Equipment Name	Automatic External Ampoules Washing, Drying & Self Adhesive Labeling Machine
Model	cGMP
Machine Capacity	350 Ampoules /min. for 1 ml ampoules .(Machine Speed Depend on Ampoules Size)
Washing ,Drying & Labeling Operation	As per Your Specification
Process	
Washing & Drying Process	As Per Your Specification
Water Storage Tank	
SS jacketed tank (for Re-circulated Water)	MOC : SS316 Filter Housing & Cartridge Drain Valve SS Piping Solenoid Valve Heater
SS jacketed tank (for Purified Water)	MOC : SS316 Filter Housing & Cartridge Drain Valve SS Piping Solenoid Valve Heater
Height Adjustment	
Height Adjustment	Manual
PLC	
Type	PLC with color HMI touch Screen
Volt	24VDC.
HMI	
Make	Allen Bradley
Power Supply	24VDC.
Other Feature	
Fault Indication System	Fault is indicated in HMI screen.
Gear Box	Make Bonfiglioli gear box with motor for machine.
Drying System	Blower Provided For Ampoule Drying.
Motor (Main)	



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Name of Components	Acceptance Criteria
Make	Bonfigolioli
Capacity	As Per your Specification
RPM	1370 RPM
Gear Box	
Make	Bonfigolioli
Ratio	As Per your Specification
AC Drive Main	
Make	Allen Bradley
Capacity	As Per your Specification
Servo Motor	
Make	Allen Bradley
Capacity	As Per your Specification
Servo Gear Box	
Ratio	As Per your Specification
Servo Drive	
Make	Allen Bradley
Capacity	800WATT.
PUMP (PW)	
Make	GRUNDFOS
Capacity	As Per your Specification
PUMP (RE.CIR)	
Make	GRUNDFOS
Capacity	As Per your Specification
Blower	
Make	AMBICA
Capacity	As Per your Specification
Modbus Module With 485	
Make	Allen Bradley
Power Supply	As Per Requirement
Out Put Module	
Make	Allen Bradley
Volt	24 volt
Temperature Module	
Make	Allen Bradley
Volt	24 volt
Temperature Sensor	
Make	As Per Your Specification
Type	RTD
Water Level Sensor	
Make	As Per Your Specification
Volt	24VDC
Heater	
Capacity	As Per Your Specification
Proximity (Door Open)	



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Name of Components	Acceptance Criteria
Make	OMRON
Ampoule Sensor	
Make	PANASONIC
Label Sensor	
Make	LEUZE
Transformer	
Make	CAMO CARE
Capacity	As Per your Specification
Pressure Switch (Pw Water)	
Make	DANFOSS
Model	KP35
Pressure Switch (Re.Cir Water)	
Model	KP35
Range	As Per Your Specification
Pressure Switch (Air)	
Make	DANFOSS
Range	As Per your Specification
Solenoid Valve (Pw Water)	
Make	ROTEX
Solenoid Valve (Re.Cir Water)	
Make	ROTEX
Valve (Air)	
Range	As Per Your Specification
Solenoid Coil (Air)	
Volt	24 VDC



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6.2 Safety Features, Alarms & Interlock: The equipment shall be provided with safety features as listed below.

S.No.	FEATURE	Acceptance criteria
1.	No Ampoule No Labeling.	No Ampoule No Labeling System is provided while machine is running in ideal condition and Ampoule is not present on Star Wheel.
2.	Emergency Stop	Machine stop
3.	Re. Cir. Temperature Low	Machine Stop
4.	Re. Cir. Water Pressure Low	Machine Stop
5.	Re. Cir. Tank Water Level Low	Machine Stop
6.	P.W. Temperature Low	Machine Stop
7.	P.W. Water Pressure Low	Machine Stop
8.	P.W. Tank Water Level Low	Machine Stop
9.	Guard Open (Washing Zone)	Machine Stop
10.	Pump Trip	Machine Stop
11.	Blower Trip	Machine Stop
12.	Main Star wheel Drive Trip	Machine Stop
13.	Air Pressure Low	Machine Stop
14.	Servo Drive Fault	Machine Stop

6.3 MATERIAL OF CONSTRUCTION:

S.No.	NAME OF COMPONENT	MOC
01.	Machine frame structure	STD
02.	External cladding	SS 304,
03.	Star Wheel	Aluminum Casting
04.	In Feed & Out worm	STD
05.	In Feed Tray	SS 304
06.	Out Feed Tray	SS 304
07.	Water Tank	SS 316



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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.



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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 Automatic External Ampoules Washing Drying & self Adhesive Labeling machine as per technical specification mentioned in the URS.
- For any changes in the design/make of the Automatic External Ampoules Washing Drying & self Adhesive Labeling machine, if not as per the URS, prior intimation/approval should be taken by the supplier from Site.
- All parts should have MOC certificates, test certificates, Calibration certificates for traceability and authenticity.



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11.0 ABBREVIATIONS:

ALM	:	Automatic External Ampoules Washing, Drying & Self Adhesive Labeling
cGEP	:	Current Good Engineering Practice
cGMP	:	Current Good Manufacturing Practice
CI.	:	Cast Iron
CQA	:	Corporate Quality Assurance
HP	:	Horse Power
Hr	:	Hour
Hz	:	Hertz
Kg	:	Kilogram
KW	:	Kilo Watt
MCB	:	Miniature circuit breaker
mm	:	Millimeter
MMI	:	Man Machine Interface
MOC	:	Material of Construction
MS	:	Mild Steel
No	:	Number
P & ID	:	Piping and Instrumentation Diagram
PO	:	Purchase Order
RPM	:	Revolution per minute
SS	:	Stainless steel
URS	:	User requirement specification
VFD	:	Variable Frequency Drive