



PHARMA DEVILS

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

URS No.:

**USER REQUIREMENT SPECIFICATION
FOR
AMPOULE FILLING MACHINE**

LOCATION	Ampoule line
SUPERSEDES URS No.	NIL



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URS No.:

CONTENTS

S.No.	TITLE	PAGE No.
1.0	APPROVAL	03
2.0	OBJECTIVE	04
3.0	SCOPE	04
4.0	RESPONSIBILITY	05
5.0	GMP / REGULATORY REQUIREMENTS	06
6.0	SYSTEM OVERVIEW	07
6.1	TECHNICAL SPECIFICATION	07-08
7.0	OTHER REQUIREMENT AND CONSTRAINTS	9
7.1	FUNCTIONAL REQUIREMENTS	9
7.2	RELIABILITY AND AVAILABILITY	9
7.3	MAINTANCE	9
8.0	LIFE CYCLE	10
8.1	DEVELOPMENT	10
8.2	TESTING	10
8.3	SUPPORT	10
8.4	DELIVERY	10
9.0	DOCUMENTS TO BE PROVIDED	11
10.0	REVIEW COMMENTS	12
11.0	ABBREVIATIONS	13



PHARMA DEVILS

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AMPOULE VERTICAL ULTRASONIC WASHING
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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)			



PHARMA DEVILS

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URS No.:

2.0 OBJECTIVE :

- This URS has been initiated by and pertains to procurement of Ampoule Filling Machine.
- 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 Filling 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 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 of the

3.0 SCOPE:

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



PHARMA DEVILS

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URS No.:

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.



PHARMA DEVILS

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URS No.:

5.0 GMP/REGULATORY REQUIREMENTS:

The Purpose of procuring Ampoule Filling Machine is to perform filling of solution as well as sealing of ampoules.

- Ampoule Filling 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 filling machine which consists of Filling and sealing Process.



PHARMA DEVILS

**USER REQUIREMENT SPECIFICATION
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URS No.:

6.1 TECHNICAL SPECIFICATION

S.No.	Name of the Component	MOC	Technical Specification
1.0	Equipment Name	-----	Filling Machine suitable for 1, 2, 3, & 5 ml ampoule with Filling & Sealing 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 L	As per cGMP Requirement
5.0	Manifold	SS316 L	As per cGMP Requirement
6.0	Conveying belt	SS304	As per cGMP Requirement
7.0	Silicone pipe	Silicone rubber	As per cGMP Requirement
8.0	Star wheel, screw conveyor and barrier, etc.	POM	As per cGMP Requirement
9.0	Filing Heads		
	No. of filling head	SS 316 L	12 Head
	MOC of filling nozzle	SS 316 L	As per cGMP Requirement
	Nitrogen Pre Purging	-----	12 Nos.
	Nitrogen Post Purging	-----	12 Nos.
10.0	Turn Table		
	MOC	SS-304	As per cGMP Requirement
	Qty.	-----	As per your specifications and as appropriate for the complete system design
	Turn table size	-----	As per your specifications and as appropriate for the complete system design
11.0	Sealing clamp		
	MOC	SS-316 L	As per cGMP Requirement
	size	-----	As per your specification
	Storage Capacity	-----	As per your specifications and as appropriate for the complete system design
	No. of cutter	-----	12
12.0	Panels	SS304	As per cGMP Requirement
13.0	Speed	-----	400 Ampoule/min in 1 ml ampoule



PHARMA DEVILS

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URS No.:

S.No.	Name of the Component	MOC	Technical Specification
14.0	Indexer	-----	As per your specification
15.0	Machine body	SS316L	Contact Parts
		SS304	Non Contacts
16.0	Motor	-----	As per your specification & suits for equipment design
	Vibrator Controllers	-----	As per your specification & suits for equipment design
	Gear Box	-----	04 Nos.
17.0	Drive	-----	AC Variable drive
18.0	Emergency Switch	-----	Push Button
19.0	Safety Features	-----	<ul style="list-style-type: none">➤ Emergency push button shall be provided.➤ Machine shall not be started without safe earthing.➤ All moving parts to be protected with safety guards.➤ door provided with interlocks.➤ Noise pollution shall be kept below 85 db.➤ Alarm should be provided
20.0	Limit Switch / Inter Locking System	-----	As per your specification
21.0	Indicating lamp	-----	As per your specification
22.0	Safety Guard	-----	As per your specification
23.0	Earthing	-----	Whole body Earthing
24.0	Utilities		
	Electrical Configuration & Cabling		
	Power Supply	-----	As per your specification and Finalized Purchase order.
	Power cable	-----	
	Power/Inverter	-----	Should be Provided as per your specification and Finalized Purchase order.
25.0	Special feature	-----	As per Purchase order.



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7.0 OTHER REQUIREMENTS AND CONSTRAINTS:

7.1 FUNCTIONAL REQUIREMENTS:

- Ampoule filling 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.



PHARMA DEVILS

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MACHINE**

URS No.:

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 Filling 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.



PHARMA DEVILS

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

URS No.:

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.



PHARMA DEVILS

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MACHINE**

URS No.:

10.0 REVIEW COMMENTS:

- For any changes in the design/make of the Ampoule Filling Machine 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)



PHARMA DEVILS

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URS No.:

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
TFM	:	Ampoule Filling machine
GA	:	General arrangement
GMP	:	Good Manufacturing Practices
Sr.	:	Senior
SS	:	Stainless steel
ISPE	:	International Society of Pharmaceutical Engineering
cGEP	:	Current Good Engineering Practices
Min	:	Minute