



PHARMA DEVILS

**USER REQUIREMENT SPECIFICATION
FOR
VIAL ALUMINUM CAP SEALING MACHINE**

URS No.:

**USER REQUIREMENT SPECIFICATION
FOR
VIAL ALUMINUM CAP SEALING
MACHINE
(DRY POWDER SECTION)**

LOCATION	DRY POWDER SECTION
SUPERSEDES URS No.	NIL



PHARMA DEVILS

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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
7.0	Other Requirement and Constraints	08
7.1	Functional Requirements	08
7.2	Reliability and Availability	08
7.3	Maintenance	08
8.0	Life Cycle	09
8.1	Development	09
8.2	Testing	09
8.3	Support	09
8.4	Delivery	09
9.0	Documents to be Provided	10
10.0	Review Comments	10
11.0	Abbreviations	11



PHARMA DEVILS

**USER REQUIREMENT SPECIFICATION
FOR
VIAL ALUMINUM CAP SEALING MACHINE**

URS No.:

1.0 APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (PRODUCTION)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



PHARMA DEVILS

**USER REQUIREMENT SPECIFICATION
FOR
VIAL ALUMINUM CAP SEALING MACHINE**

URS No.:

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 Vial Aluminum Cap Sealing 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 Vial Aluminum Cap Sealing 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 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 Vial Aluminum Cap Sealing Machine of Site.
- 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

**USER REQUIREMENT SPECIFICATION
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VIAL ALUMINUM CAP SEALING MACHINE**

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

**USER REQUIREMENT SPECIFICATION
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VIAL ALUMINUM CAP SEALING MACHINE**

URS No.:

5.0 GMP/REGULATORY REQUIREMENTS:

The Purpose of procuring Vial Aluminum Cap Sealing Machine is to perform sealing of glass vials in Dry Powder Section.

- Vial Aluminum Cap Sealing Machine should comply with the “Current Good Manufacturing Practices”.
- Schedule–M “Good Laboratory Practices and Requirements of Premises, Plant & Equipments for Pharmaceuticals Products”.



PHARMA DEVILS

**USER REQUIREMENT SPECIFICATION
FOR
VIAL ALUMINUM CAP SEALING MACHINE**

URS No.:

6.0 SYSTEM OVERVIEW:

Automatic High Speed Eight Heads Vial Aluminum Cap Sealing Machine should be suitable for sealing of vials with 20 mm Aluminum Caps.

6.1 TECHNICAL SPECIFICATION

S.No.	Name of the Component	MOC	Technical Specification
1.0	Equipment Name	----	Automatic High Speed Vial Aluminum Cap Sealing Machine
2.0	Modal /Type	----	AHCS – 350.
3.0	No. of head	----	8
4.0	Speed	----	240 vials /minute (for 10ml)
5.0	Emergency Switch	----	Push Button
6.0	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. ➤ All upper guards provided with interlocks. ➤ Noise pollution shall be kept below 85 db. ➤ Alarm should be provided
7.0	Limit Switch / Inter Locking System	----	As per your specification
8.0	Indicating lamp	----	As per your specification
9.0	Safety Guard	----	As per your specification
10.0	Earthing	----	Whole body Earthing
11.0	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.	
12.0	Special feature	----	As per Purchase order.



PHARMA DEVILS

**USER REQUIREMENT SPECIFICATION
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VIAL ALUMINUM CAP SEALING MACHINE**

URS No.:

7.0 OTHER REQUIREMENTS AND CONSTRAINTS:

- Parts coming in contact with the container or the Aluminium Cap or exposed to the atmosphere should be made out of Stainless Steel for long life.
- Single Motor synchronizes Conveyor, Star Wheels and Platform Turret and the speed should be varied by VFD.
- Infeed/Exit Star Wheel should be equipped with safety clutch for automatic stoppage of machine in case of jamming and / or overloading.
- No Cap in Chute – Machine Stop mechanism.
- PLC with 3 Level password
- Inbuilt Pulse Counter.
- Container Overturn – Machine Stop mechanism.
- Spring loaded free spinning Sealing Rollers eliminate any damage to Aluminium Caps and allows greater flexibility of variation in the container neck dia.
- Unique Sealing Rollers impart uniform, scratch free, fit tight and reliable skirting and sealing.
- No Rubber Stopper – Vial Reject system
- Pop Up Rubber Stopper – Vial Reject system
- No Cap – Vial Reject system

7.1 FUNCTIONAL REQUIREMENTS:

- Vial Aluminum Cap Sealing Machine must comply as per ISPE and cGMP 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

**USER REQUIREMENT SPECIFICATION
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VIAL ALUMINUM CAP SEALING 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 Vial Aluminum Cap Sealing 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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VIAL ALUMINUM CAP SEALING 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.

10.0 REVIEW COMMENTS:

- For any changes in the design/make of Vial Aluminum Cap Sealing 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



PHARMA DEVILS

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VIAL ALUMINUM CAP SEALING MACHINE**

URS No.:

11.0 Abbreviations:

URS	USER REQUIREMENT SPECIFICATION
cGMP	Current good manufacturing practices
GMP	good manufacturing practices
MOC	Material of construction
SS	Stainless steel
ISPE	International society of pharmaceutical engineering
DQ	Design qualification
QA	Quality assurance