USER REQUIREMENT SPECIFICATION FOR AUTOMATIC EIGHT HEAD VIAL SEALING MACHINE (DRY POWDER SECTION)

LOCATION	**VIAL SEALING ROOM (DRY POWDER SECTION)**
SUPERSEDES URS No.	

URS CONTENTS

PHARMA DEVILS	USER REQUIREMENT SPECIFICATION FOR AUTOMATIC EIGHT HEAD VIAL SEALING MACHINE	URS No.:

1.0 PREPARATION, REVIEW AND APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (PRODUCTION)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

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 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 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 by the 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 Vial Aluminum 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.

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	• Co-ordination with User Department to prepare User Requirement Specification. • To check the completeness and Technical Accuracy of the URS. • Review and Authorization of User Requirement Specification for compliance with the Product Requirement.
Production	• Preparation and Approval of User Requirement Specification. • Review of User Requirement Specification for compliance with the Product Requirement
Engineering	• Review of User Requirement Specification. • Assist in preparation of User Requirement Specification.

5.0 GMP/REGULATORY REQUIREMENTS:

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

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

6.0 SYSTEM OVERVIEW:

Automatic Eight Heads Vial Aluminum Sealing Machine should be suitable for sealing of vials with 20 mm Aluminum Seals.

6.1 TECHNICAL SPECIFICATION:

S.No.	Name of the Component	MOC	Technical Specification
1.0	Equipment Name	-----	Automatic Eight head Vial Sealing Machine
2.0	Modal /Type	-----	NKCS – 350
3.0	No. of head	----	8 Heads
4.0	Speed	-----	250 vials /minute (for 5 & 10 ml)
5.0	Emergency Switch	-----	Push Button
6.0	Safety Features	-----	➢ 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 standard specification
8.0	Indicating lamp	-----	As per standard specification
9.0	Safety Guard	-----	As per standard specification
10.0	Earthing	-----	Whole body earthing
11.0	**Utilities**		
	Electrical Configuration & Cabling		
	Power Supply	-----	As per standard specification and Finalized Purchase order.
	Power cable	-----	
	Power / Inverter	-----	Should be Provided as per standard specification and Finalized Purchase order.
12.0	Special feature	-----	As per Purchase order.

7.0 OTHER REQUIREMENTS AND CONSTRAINTS:

- Parts coming in contact with the container or the Aluminum Seal 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.
- In feed/Exit Star Wheel should be equipped with safety clutch for automatic stoppage of machine in case of jamming and / or overloading.
- No Seal in Chute – Machine Stop mechanism.
- No stopper on vial before sealing machine stop sensor
- PLC with 3 Level passwords.
- Inbuilt Pulse Counter.
- Container Overturn – Machine Stop mechanism.
- Spring loaded free spinning Sealing Rollers eliminate any damage to Aluminum Seals 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 Seal – Vial Reject system

7.1 FUNCTIONAL REQUIREMENTS:

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

7.2 RELIABILITY :

- 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.

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 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.

9.0 DOCUMENTS TO BE PROVIDED:

- All MOC Certificates, Manual for Bought out items.
- Design Qualification and FAT protocol at the time of FAT.
- Installation Qualification protocol.
- Operational Qualification protocol.
- Schematic Diagram of machine showing Overall Dimensions.
- Instrument list with manufacturer’s calibration certificate.
- G.A & Electrical 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 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.

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Approved By:_____
Head QA
Sign/Date