



**USER REQUIREMENT SPECIFICATION
FOR AUTOMATIC HIGH SPEED SELF ADHESIVE
(STICKER) ROUND CONTAINER LABELING
MACHINE**

URS No.:

**USER REQUIREMENT SPECIFICATION
FOR
AUTOMATIC HIGH SPEED SELF
ADHESIVE (STICKER) ROUND
CONTAINER LABELING MACHINE**

LOCATION	DRY POWDER SECTION
SUPERSEDES URS No.	NIL



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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)			



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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 Automatic High Speed Self Adhesive (Sticker) 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 Automatic High Speed Self Adhesive (Sticker) Round Container 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 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.

3.0 SCOPE:

- The scope of this document is limited to the User Requirement Specification (URS) of Automatic High Speed Self Adhesive (Sticker) Round Container Labeling Machine.
- 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 Automatic High Speed Self Adhesive (Sticker) Round Container Labeling Machine is to perform sticker labeling of glass vials in Dry Powder Section.

- Automatic High Speed Self Adhesive (Sticker) Round Container Labeling Machine should comply with the “Current Good Manufacturing Practices”.
- Schedule–M “Good Laboratory Practices and Requirements of Premises, Plant & Equipments for Pharmaceuticals Products”.



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6.0 SYSTEM OVERVIEW:

Automatic High Speed Self Adhesive (Sticker) Round Container Labeling Machine should be suitable for labeling of glass vials.

6.1 TECHNICAL SPECIFICATION:

S.No.	Name of the Component	MOC	Technical Specification
1.0	Equipment Name	----	Automatic High Speed Self Adhesive (Sticker) Round Container Labeling Machine
2.0	Modal /Type	----	AHL – 300SA
3.0	Speed	----	200 vials /minute (for 5/10/15ml)
4.0	Emergency Switch	----	Push Button
5.0	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
6.0	Limit Switch / Inter Locking System	----	As per your specification
7.0	Indicating lamp	----	As per your specification
8.0	Safety Guard	----	As per your specification
9.0	Earthing	----	Whole body Earthing
10.0	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.	
11.0	Special feature	----	As per Purchase order.



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7.0 OTHER REQUIREMENTS AND CONSTRAINTS:

- Fully S.S. 304 pipe frame structure with electrical panel made from S.S.304
- Compact Design with straight way operations.
- Servo based label dispensing unit.
- Variable drives for pressing & conveyor assembly.
- PLC for error free operations.
- PLC for 3 Level password
- Feather touches HMI for easy access of machine controls.
- AC Frequency Drive for Speed Control.
- Counter on the HMI.
- No container – No label system avoids wastage of labels.
- Label Roll empty alarm with machine stop system.
- No need to enter any sort of parameters like label length/width.
- Single container separator for every size of containers.
- Label Roll Ending Alarm System.
- No Container – No Label System.
- Inkjet Printer having 12.5mm printing Height and 140mm printing Length on Porous Material.
- Camera system should be for checking of Coding, Missing of Labels & Bar Code.
- Camera system should be provided if any error, machine stop system.
- Rejection system should be provided for missing label Container rejection System.
- Rejection system should be provided for improper coding Container rejection System.
- Rejection system should be provided for 2D Code / Barcode Scanner for Rejection System.

7.1 FUNCTIONAL REQUIREMENTS:

- Automatic High Speed Self Adhesive (Sticker) Round Container Labeling 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.



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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 Automatic High Speed Self Adhesive (Sticker) Round Container Labeling 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.

10.0 REVIEW COMMENTS:

- For any changes in the design/make of Automatic High Speed Self Adhesive (Sticker) Round Container Labeling Machine if not as per the URS, prior intimation/approval should be taken by the supplier.
- 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:

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