USER REQUIREMENT SPECIFICATION FOR AUTOMATIC SELF ADHESIVE VERTICAL LABELING MACHINE (DRY POWDER SECTION)

LOCATION	**PACKING HALL (DRY POWDER SECTION)**
SUPERSEDES URS No.	

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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 Automatic Self Adhesive Vertical Labeling 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 Automatic Self Adhesive Vertical 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 of the site.

3.0 SCOPE:

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

- Automatic Self Adhesive Vertical Labeling 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 Self Adhesive Vertical 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 Self Adhesive Vertical Labeling Machine.
2.0	Modal /Type	-----	ATL – 250CR
3.0	Speed	-----	220-250 vials /minute (for 10ml)
4.0	Emergency Switch	-----	Push Button
5.0	Safety Features	-----	➢ Emergency push button shall be provided. ➢ Machine shall not be started without safe earthling. ➢ All moving parts to be protected with safety guards. ➢ Noise pollution shall be kept below 85 db. ➢ Alarm should be provided
6.0	Limit Switch / Inter Locking System	-----	As per Standard specification
7.0	Indicating lamp	-----	As per Standard specification
8.0	Safety Guard	-----	As per Standard specification
9.0	Earthing	-----	Whole body Earthing.
10.0	**Utilities**		
	Electrical Configuration & Cabling		
	Power Supply	-----	As per Standard 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.

7.0 OTHER REQUIREMENTS AND CONSTRAINTS:

- cGMP Model
- Sensor for Label & Container
- Label Roll Ending alarm system
- Sensor for No Vial No Label.
- Sensor for minimum Accumulation at in feed, machine stop with auto restart.
- Sensor for maximum Accumulation at out feed, Machine stop with auto restart.
- Machine is suitable to synchronized with Printer and Vision system with the help of slot sensor- 2 nos. (In case of printer and vision system)
- Low Air, Machine Stop.
- Sensor for detection of fallen vial on conveyor before Labelling with machine stop facility.
- Rejection Bin full detection sensor (In case of rejection system)
- Machine set parameter/ Event log/Batch summary/Report generation system
- Maximum rejection, machine stop system
- Recipe System
- Servo Drive fault, machine stop system
- Camera stop, machine stop system
- Conveyor Drive Fault machine stop
- Emergency stop machine stop
- Feeder drive fault machine stop

7.1 FUNCTIONAL REQUIREMENTS:

- Automatic Self Adhesive Vertical Labeling 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 Automatic Self Adhesive Vertical 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.

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 Automatic Self Adhesive Vertical 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.

Approved By:_____
Head QA
Sign/Date