USER REQUIREMENTS SPECIFICATION FOR AUTOMATIC SELF ADHESIVE VERTICAL LABELING MACHINE

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1.0 Introduction:

This document prepared to provide user requirement specification for equipment. This document covers the technical specification for equipment **Automatic Self Adhesive Vertical labeling Machine**
This is important for equipment that is part of integrated process or line and will help supplier to understand the user's requirements.

2.0 Overview:

2.1 Intended use

2.1.1 For pharmaceutical products

2.2 Production Capacity

2.2.1 The Capacity Of The **Automatic Self Adhesive Vertical Labeling Machine** is to be 25-300 Kg/Hrs (through 1 mm sieve approx..)

2.3 Space Availability

2.3.1 Allocated floor space for the machine is 870 mm X 900 mm and vertical clearance is 3800 mm

2.4 Accuracy of instrumentation desired:

2.4.1 Not Applicable

2.5 Cleaning requirement:

2.5.1 Easy to clean (easily accessible for cleaning & clean in place)

2.6 Equipment specific requirement

2.6.1 It should be designed to meet latest cGMP standards & should have low maintenance cost.

2.6.2 Equipment shall have

- Label Dispensing Device
- Pressing Device
- Conveyor Belt Assembly
- Servo motor
- Release paper collect roller

2.6.3 All the contacts parts made up of SS304 with mirror polish.

2.6.4 Automatic Self Adhesive Vertical Labeling Machine should be provided with 2HP

2.6.5 Spare parts required:
NA

3.0 Operational Requirements:

3.1 Functional Requirements

3.1.1 Operation

3.1.1.1 All control will be positioned where the operator has a full view of the system/equipment.

3.1.1.2 Operation shall be safe from an operator and environment standpoint.

3.1.2 Control System Requirements

3.1.2.1 Operator message display terminals are preferred with warnings lamps.

3.1.2.2 There should be an "ON", "OFF", "INCH" switch. And speed regulator. Indicator lamp for clutch, selector switch for light ON/OFF.

3.1.2.3 All devices and wiring which are located inside of operation panel will be suitably protected from physical damage.

3.1.3 Alarms and Warnings

3.1.3.1 No round container no labeling sensor
Emergency Stop
Servo Alarm
No round container
Vial Jam
Label Roll Empty
Feeder drive fault
Conveyor Drive Fault
Pressing Belt Drive Fault

3.1.4 Power failure / Recovery

3.1.4.1 In the event of a power failure, the system shall protect in the following priority:
Personnel
Equipment
Product

3.1.4.2 In the event of a power failure, the system shall stop automatically and will require operator intervention to re-start.

3.1.5 Safety Requirements

3.1.5.1 Grounding: Proper earthing should be provided. Micro switch & emergency stop

3.2 Environment

3.2.1 Automatic Visual Vial Inspection Machine will be installed in an environment with a temperature range of NMT 25°C & % RH of NMT 60%.

3.3 Other requirements

3.3.1 M. O.C.- Non contacts parts-MS cladded with SS304 mirror polish.

4.0 Compatibility and Support:

4.1 Utilities

4.1.1 The supplier shall indicate the requirement of utilities to be provided by the user while submitting the design specification.

4.1.2 Base Utilities Worksheet:
230V (±10%) single phase, AC, 50 Hz

4.1.3 Other utility requirements shall be discussed as needed.

4.2 Availability

4.2.1 Automatic Visual Vial Inspection Machine is intended to be operated: Regularly.

4.3 Procedural document requirements

4.3.1 Supplier has to provide,

- Detailed functional specification
- Design Qualification, Installation Qualification, Operational Qualification
- Material Test Certificate for Contact parts
- Surface Finish Test Report
- Installation, operation & maintenance Manual with spare List
- Warranty Certificate of machine ,
- Certificates & Manuals of brought out items including calibration

4.4 Process requirements:
For Pharmaceutical products

4.5 Data and Security

4.5.1 Controls provided with Data Collection systems shall be required to meet **21 CFR Part 11 compliance**
-Audit trail facility is required.

4.5.2 User interface access levels/level of automation
NA

4.5.3 Language requirements
English

4.5.4 Display Requirements-
NA

4.5.5 Interface with other equipment
NA

4.5.6 Data collection (archiving & reporting requirements)
NA

5.0 Constraints:

5.1 Milestones and Timelines

5.1.1 The Supplier shall notify the User three weeks in advance of the start of Factory acceptance test.
The Factory Acceptance Test Specification shall be submitted to the User for review and approval prior to execution. A minimum of two weeks weeks shall be allowed for the User to review and to comment and/or approve the Factory Acceptance Test Specification.
The User shall notify the Supplier of the length of runs required, special materials required, and any other unique test requirements two weeks in advance of the start of testing.

5.2 Equipment Constraints

5.2.1 Noise Level Constraints:
NA

5.2.2 Preferred Vendor List:
NA

5.3 Labelling

5.3.1 All equipment and control wiring shall be labeled and identified.

5.4 Testing

5.4.1 In order to verify system performance, the User shall witness the execution of the Factory Acceptance Test procedures.

5.5 Delivery

5.5.1 All final documents shall be shipped with transmittals that identify them as contractually required documents. All final documents and drawings shall reflect "as-built" condition

5.5.2 All documents shall in the language of the English and supplied with hard copies and electronic versions supplied in the format identified for each document.

5.6 Support

5.6.1 Start-up Support:

- Training

5.6.2 Post Start-up Support:

Technical Support:

- Telephone
- Replacement Parts Availability List

User Site Support

- Preventative Maintenance (list maintenance contracts available)
- System Improvements (supplier shall notify user of any improvements available on a regular basis.

6.0 Abbreviation:

Acronym	Definition
°C	Degrees Celsius
db	Decibel
%	Percentage
URS	User Requirement Specification

7.0 References:

Nil

8.0 Attachments:

Nil

9.0 Approvals:

	Name	Designation	Sign	Date
Prepared by				
Checked by				
Approved by				
Authorized by				