USER REQUIREMENT

SPECIFICATION

FOR

STICKER LABELLING MACHINE

LOCATION	**THREE PIECE LINE**
SUPERSEDES URS No.	**NIL**

PHARMA DEVILS	USER REQUIREMENT SPECIFICATION FOR STICKER LABELLING MACHINE	URS No.:

USER CONTENTS

PHARMA DEVILS	USER REQUIREMENT SPECIFICATION FOR STICKER LABELLING MACHINE	URS No.:

1.0 APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (USER DEPARTMENT)			
HEAD (ENGINEERING)			

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 Equipments, Cleaning/Proper Maintenance, cGMP, Safety and Regulatory Requirements necessary to construct and fabricate a sticker 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 sticker 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 by the Site, will become a Contractual Agreement between Vendor and the Site.
- This URS will 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 sticker labeling machine at the Sit.
- The URS shall be used as a reference document for considering all aspects of Current Good Manufacturing Practices (cGMP) and Safety.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments shall be responsible for the overall compliance of this URS.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Initiation & 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	• 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 Sticker labelling is to label the plastic three piece filled Vials,
- Sticker labeling machine should comply with the “Current Good Manufacturing Practices”.
- WHO GMP- “Good Manufacturing for Pharmaceutical Products”.
- Schedule–M - “Good Manufacturing Practices and Requirements of Premises, Plant & Equipments for Pharmaceuticals Products”.

6.0 SYSTEM OVERVIEW:

6.1 TECHNICAL SPECIFICATION

S.No.	Critical Variables	MOC	Acceptance Criteria
1.	Equipment	SS304	Sticker labeling Machine
2.	Overall Dimensions	…….	As per party specification
3.	Label Speed	…….	Approx 200 CPM
4.	Label Dispenser	…….	As per your specifications and as appropriate for the complete system design.
5.	Start / Stop Button	…….	Green/ Red
	Make		ISO Certified.
	Type		Push.
6.	Label Widh (height) Range	…….	10 To 100 mm.
7.	Label Length Range	…….	10 to 300 mm
8.	Label Pressing System	…….	Wrap Around System
9.	Main Drive Motor	…….	As per your specifications and as appropriate for the complete system design.
10.	Gear Box	…….	As per your specifications and as appropriate for the complete system design.
11.	Label Sensor	…….	As per your specifications and as appropriate for the complete system design tosense the presence of container for labeling.
12.	Label Release Plate	SS304	cGMP requirement
13.	Label Pressing plate	Aluminum lined	cGMP requirement
14.	Main Body & Top plate	SS304	cGMP requirement

7.0 OTHER REQUIREMENTS AND CONSTRAINTS:

7.1 FUNCTIONAL REQUIREMENTS:

- Sticker labeling machine shall comply as per ISPE, cGMP, cGEP 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.

8 LIFE CYCLE:

8.1 DEVELOPMENT

- The supplier shall follow cGMP practices in design, development, construction and Installation of the system.

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, procedure and Operator training.
- Supplier shall provide support during Installation, Operation.

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 other qualification documents (DQ, IQ, OQ) in Soft as well as Hard Copy.
- Operating Manual.

9 DOCUMENTS TO BE PROVIDED :

- All MOC Certificates, Manual for Bought out items
- Design Qualification protocol.
- Installation Qualification protocol.
- Operational Qualification protocol.
- 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 REVIEW COMMENTS:

- The supplier should make/design the sticker labeling machine as per technical specification mentioned in the URS.
- For any changes in the design/make of the sticker labeling 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

11 ABBREVIATIONS:

URS	:	User Requirement Specification
cGMP	:	Current Good Manufacturing Practices
ISPE	:	International Society of Pharmaceutical Engineering
cGEP	:	Current Good Engineering Practices
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
MOC	:	Material of Construction
WHO GMP	:	World Health Organization Good Manufacturing Practices
ISO	:	Indian standard organization
QA	:	Quality Assurance
GA	:	General arrangement
GMP	:	Good Manufacturing Practices
Sr.	:	Senior
SS	:	Stainless steel
SLM	:	Sticker labeling machine