USER REQUIREMENT SPECIFICATION

FOR

BOPP TAPING MACHINE

LOCATION	**DRY POWDER LINE**
SUPERSEDES URS No.	**NIL**

CONTENTS

PHARMA DEVILS	USER REQUIREMENT SPECIFICATION FOR BOPP TAPING MACHINE	PROTOCOL No.:

1.0 APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
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 Instruments, Cleaning / Proper Maintenance, cGMP, Safety and Regulatory Requirements necessary to construct and fabricate a functional BOPP Taping 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 Three Piece Filling 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 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 BOPP Taping Machine of the Sit.
- 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	• 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	• Review of User Requirement Specification for compliance with the Product Requirement.

5.0 GMP/REGULATORY REQUIREMENTS:

BOPP Taping Machine used for simultaneous application of BOPP tape on top and bottom of the shipper. in injection Block of the Site.

- BOPP Taping Machine should complies with the “Current Good Manufacturing Practices”.
- Schedule–M “Good Laboratory Practices and Requirements of Premises, Plant & Equipments for Pharmaceuticals Products”.

6.0 SYSTEM OVERVIEW:

BOPP Taping Machine used for simultaneous application of BOPP tape on top and bottom of the shipper. BOPP Taping Machine is a cGMP model with automatic height and width adjustment system to accommodate different shipper size. Useful machine for production lines having random shipper size.

6.1 TECHNICAL SPECIFICATION

S.No.	Name of the Component	MOC	Technical Specification
1.0	Equipment Name	-----	BOPP Taping Machine
2.0	Modal /Type	-----	Should be in compliance with cGMP.
3.0	Overall Size of the Machine	-----	As per your specification
4.0	Tape Width	-----	2 Inches (3 Inches optional)
5.0	Sealing speed	-----	Approx 20 mtrs / min
6.0	Strap width	-----	15 mm
7.0	Strap Tension	-----	Max. 70 kgs
8.0	Strapping Speed	-----	3.6 sec / strap
9.0	Loading Weight	-----	Approx 2000 kgs

7.0 OTHER REQUIREMENTS AND CONSTRAINTS:

➢ FUNCTIONAL REQUIREMENTS:

- BOPP Taping Machine shall comply as per ISPE, cGMP, cGEP Guidelines.

➢ RELIABILITY AND AVAILABILITY:

- The system shall be available for continuous operation.
- Material of construction used shall be suitable for the intended service so as to withstand the working stress without frequent break down.

➢ MAINTENANCE:

- The system shall allow for maintenance by trained site personnel with supplier recommended tools and practices.
- 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 BOPP Taping 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.

- **DOCUMENTS TO BE PROVIDED:**
- 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.

9.0 REVIEW COMMENTS:

- For any changes in the design/make of the BOPP Taping 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)

10.0 ABBREVIATIONS:

URS	:	User Requirement Specification
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
MOC	:	Material of Construction
cGMP	:	Current Good Manufacturing Practices
HP	:	Horse power
TFM	:	Three Piece Filling machine
Hz	:	Hertz
AC	:	Alternative Current