



PHARMA DEVILS

DESIGN QUALIFICATION PROTOCOL CUM REPORT

PROTOCOL No.:

**FOR
BOPP TAPING MACHINE**

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DATE OF QUALIFICATION

SUPERSEDE PROTOCOL No.

NIL



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1.0 PRE – 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)			



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2.0 OBJECTIVE:

- To prepare the Design Qualification on the basis of URS, Purchase Order and information given by Supplier.
- The purpose of Design qualification is to ensure that all Critical Aspects of Process/Product requirement, cGMP and Safety have been considered in designing the equipment and is properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification for **BOPP Taping Machine (Make:)** to be installed.
- The equipment shall operate under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & ID's provided by vendor shall be verified during Design Qualification.



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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 Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Initiation, Review and Approval of the Qualification Protocol cum Report• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.• Review of Qualification Protocol cum Report after Execution.• Co-ordination with Production and Engineering to carryout Design Qualification.• Monitoring of Design Qualification Activity.• Review of Qualification Protocol cum Report after Execution.
Production	<ul style="list-style-type: none">• Review of the Protocol cum Report.• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.• Review of Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review of the Qualification Protocol cum Report• Assist in the Preparation of the Protocol cum Report.• To co-ordinate and support the Activity.• To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e.<ul style="list-style-type: none">➤ GA Drawing.➤ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/brochures.➤ Details of utilities Required.➤ Identification of components for calibration.➤ Material of construction of Product Contact Parts.➤ Brief Process Description.➤ Safety Features and Alarms.• Review of Qualification Protocol cum Report after Execution.



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5.0 BRIEF PROCESS DESCRIPTION:

BOPP Taping Machine used for simultaneous application of BOPP tape on top and bottom of the shipper. Independent two motors for ensuring smooth operation for extra light and heavy shippers. 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. Some of the silent features of BOPP Tape Machine are as below:

- Automatically Operated.
- Manually adjustable box height and box width.
- Top & bottom belt drive for smooth & reliable taping.
- Sturdy and strong construction.
- Proper functioning.
- Application specific design.

6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared for the manufacturer of equipment ensures complies with User Requirement Specification.



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7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS/PRODUCT PARAMETERS:

Critical Variables	Acceptance Criteria	Reference
Application: The BOPP Taping Machine should be able to provide simultaneous application of BOPP tape on top and bottom of the shipper.	BOPP Taping Machine should be able to provide simultaneous application of BOPP tape on top and bottom of the shipper.	Process Requirement
Working: Working of BOPP Taping Machine.	The BOPP Taping Machine should be able to provide simultaneous application of BOPP tape on top and bottom of the shipper.	Process Requirement

7.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

Critical Variables	Acceptance Criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply:	The electrical system of the equipment shall be housed as per the cGMP and cGEP standards, with adequate safety. Electrical panel and electro pneumatic panel is to be installed in service area.	GMP Requirement
Room Condition	Temperature and RH required as per requirement of product.	Process Requirement



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7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

S. No.	Critical Variables	Acceptance Criteria
1.	Equipment	BOPP Taping Machine
2.	Model	SP102 TU/FXJ 6050 (Uniform Model)
3.	Main Motor	Nos. : 02 Make : V MAILI (CE) Power : 240 W Electric Supply : 50 Hz, 0.68 A, 220 V, 1350 RPM.
4.	Maximum Sealing Dimension (W, AH, AL) (in mm)	500, A 500, A 600
5.	Minimum Sealing Dimension (W, AH, AL) (in mm)	120, A 180, A 300
6.	Speed of Sealing Belt (m/min.)	16.3
7.	Working Table Height (mm)	830
8.	With Adhesive tape for sealing (mm)	48, 60, 76
9.	Dimension (L, AW, AH) (in mm)	2665, A 1100, A 1555 (With extended Conveyor)
10.	Weight	120 Kg
11.	MCB	Make : L & T Type : C 16 Volt : 240/415 V
12.	Castor Wheel	Nos. : 04



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7.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material of Construction	Reference
1.	Motor	STD	Process Requirement
2.	Gear box	STD	Process Requirement
3.	Machine Frame	SS 304	GMP Requirement
4.	Covers	SS 304	GMP Requirement
5.	Castor Wheel	Polyurethane (PU)	GMP Requirement

7.5 SAFETY:

Critical Variables	Acceptance Criteria	Reference
MCB	MCB is provided so that when there is an overload in current or any short circuit then the MCB trips.	Safety Requirement
Mechanical Guard	Mechanical guard for all rotating parts.	Safety Requirement
Joints	Welding of joints without any welding burrs.	Safety Requirement
Metal Parts	All the metal parts should be properly grounded without any sharp edges.	Safety Requirement
Leveling and Balancing	Equipment should be properly balanced & leveled.	Safety Requirement
Electrical Wiring and Earthing	Electrical wiring should be as per approved drawings. Double external Earthing to control machine panel and motors and operator should be provided.	Safety Requirement
Noise Level	Below 80 db	Safety Requirement

7.6 VENDOR SELECTION:

Critical Variables	Acceptance Criteria	Reference
Selection of Vendor for supplying the Swing Conveyor.	Selection of Vendor is done on the basis of review of vendor. Criteria for review were vendor background (general/financial), technical know how, quality standards, inspection of site, costing, feedback from market (customers already using the equipment).	Process Requirement

Reference: (1) The equipment shall conform to the specifications and requirements.
(2) Operating and service manual for BOPP Taping Machine.



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8.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the supplier, if any.
- Purchase Order Copy.
- Any other relevant documents.

9.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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10.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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12.0 ABBREVIATIONS:

URS	:	User Requirement Specification
cGMP	:	Current Good Manufacturing Practice
cGEP	:	Current Good Engineering Practice
PO	:	Purchase Order
DQ	:	Design Qualification
Kg	:	Kilogram
mm	:	Millimeter
SS	:	Stainless Steel
MOC	:	Material of Construction
BOPP	:	Biaxially Oriented Polypropylene
GA	:	General Arrangement
P & ID	:	Piping and Instrumentation Diagram
MCB	:	Miniature Circuit Breaker
db	:	Decibel
RH	:	Relative Humidity
RPM	:	Revolution per Minute
HP	:	Horse Power
A	:	Adjustable
AMP	:	Ampere
STD	:	Standard
BTM	:	BOPP Taping Machine
V	:	Volt
Hz	:	Hertz

13.0 REVIEWED BY:



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DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

AUTHORIZED BY:

DESIGNATION	NAME	SIGNATURE	DATE
Sr. GENERAL MANAGER (QUALITY ASSURANCE)			