



PHARMA DEVILS

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
BOPP TAPING MACHINE**

PROTOCOL No.:

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
BOPP TAPING MACHINE**

EQUIPMENT ID. No.	
LOCATION	Packing Hall
DATE OF QUALIFICATION	
SUPERSEDES 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 carry out the Installation Qualification of BOPP Taping Machine to provide simultaneous application of BOPP tape on top and bottom of the carton.
- To confirm that the equipment and its components are as per the Specifications and installed as per the Approved Design and complies with cGMP practices.
- To ensure that there is sufficient information available to operate and maintain the equipment safely, effectively and consistently.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of **BOPP Taping Machine (Make:)** to be installed.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required for installation qualification activity.



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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, Approval and Compilation of the Installation Qualification Protocol cum Report.• Co-ordination with Production and Engineering to carryout Installation Qualification.• Monitoring of Installation Qualification Activity.
Production	<ul style="list-style-type: none">• Review & Pre Approval of Protocol cum Report.• To Co-ordinate and support for Execution of Qualification study as per Protocol.• Post Approval of Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review & Pre Approval of Protocol cum Report.• Co-ordination, Execution and technical support in BOPP Taping Machine Installation Qualification Activity.• Calibration of Process Instruments.• Responsible for Trouble Shooting (if occurs during execution).• Post Approval of Qualification Protocol cum Report after Execution.



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5.0 EQUIPMENT DETAILS:

Equipment Name	BOPP Taping Machine
Equipment	
Manufacturer's Name	
Model	
Supplier's Name	
Location of Installation	Packing Hall

6.0 SYSTEM 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.



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7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents :

- Executed and approved design qualification document.
- Piping and Instrumentation Diagram (P& ID).
- Electrical Circuits Diagram.
- Technical Specification of Equipment.
- Calibration Certificate of Components.
- Certificate of Material of Construction of Components.

7.1.1 Procedure:

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum Report.

7.1.2 Acceptance Criteria:

- All the documents should be available, complete and approved by respective authorities.



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8.0 CRITICAL VARIABLES TO BE MET:

8.1 Installation Qualification Checklist:

S.No.	Installation Check	Observation	Observed by (Engineering) Sign/Date
1.	Check the proper mechanical installation of BOPP Taping Machine.		
2.	Check the proper electrical installation of BOPP Taping Machine.		
3.	Check the parts are working properly.		
4.	Check the equipment is free from any defects.		
5.	Check the finishing of machine parts.		

**Checked By
(Production)
Sign/Date:**

**Verified By
(Quality Assurance)
Sign/Date:**

Inference:

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**Reviewed By
(Manager QA)
Sign/Date:**



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8.2 General Checks and Location Suitability:

S.No.	Installation Checks	Acceptance Criteria	Observation	Observed by (Engineering) Sign/Date
1.	Grouting and Mounting	Should be grouted and mounted properly.		
2.	Leveling	Should be properly balanced and leveled.		
3.	Edges of Parts	Metal edges should be properly rounded off without any sharp edges.		
4.	Welding of Joints	Welding of joints should be without any welding burrs.		
5.	Place of Installation	Packing Hall		
6.	Room Condition	General working condition. As per GMP and production requirement.		
7.	Illumination	NLT 300 Lux.		
8.	Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

Checked By (Production)
Sign/Date:

Verified By (Quality Assurance)
Sign/Date:

Inference:

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Reviewed By (Manager QA)
Sign/Date:



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8.3 Installation Checks:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Equipment	BOPP Taping Machine		
Model	SP102 TU/FXJ 6050 (Uniform Model)		
Main Motor	Nos. : 02 Make : V MAILI (CE) Power : 240 W Electric Supply : 50 Hz, 0.68 A, 220 V, 1350 RPM.		
Maximum Sealing Dimension (W, AH, AL) (in mm)	500, A 500, A 600		
Minimum Sealing Dimension (W, AH, AL) (in mm)	120, A 180, A 300		
Speed of Sealing Belt (m/min.)	16.3		
Working Table Height (mm)	830		
With Adhesive tape for sealing (mm)	48, 60, 76.		
Dimension (L, AW, AH) (in mm)	2665, A 1100, A 1555 (With extended Conveyor)		
Weight	120 Kg		
MCB	Make : L & T Type : C 16 Volt : 240/415 V		
Castor Wheel	Nos. : 04		

**Checked By
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Sign/Date:**

**Verified By
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Sign/Date:**

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8.4 MOC Verification List:

S.No.	Parts Name	Material of construction	Observation	Observed By (Engineering) Sign/Date
1.	Motor	STD		
2.	Gear box	STD		
3.	Machine Frame	SS 304		
4.	Covers	SS 304		
5.	Castor Wheel	Polyurethane (PU)		

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Sign/Date:**

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Sign/Date:**



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8.5 Safety:

Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Well embedded equipment	For BOPP Taping Machine.		
MCB	MCB is provided so that when there is an overload in current or any short circuit then the MCB trips.		
Electrical wiring and Earthing.	Electrical wiring should be as per approved drawings. Double external earthing to control machine panel and motors should be provided.		
Safety Guards	Guards for all moving parts should be provided for safety.		
Start On/Off switch: To Stop the process immediately.	Should be provided for equipment and operator safety.		
Noise Level	Below 80 db		

**Checked By
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Sign/Date:**

**Verified By
(Quality Assurance)
Sign/Date:**

Inference:

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Sign/Date:**



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9.0 REFERENCES:

The Principle Reference is the following:

Validation Master Plan

- Schedule-M – “Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.”
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2 – Good Manufacturing Practices and Inspection.

10.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC.
- Calibration certificates.
- Operation and Maintenance Manual.



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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

No.	:	Number
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
MOC	:	Material of construction
cGMP	:	Current Good Manufacturing Practices
EU	:	European Union
DQ	:	Design Qualification
IQ	:	Installation Qualification
mm	:	Millimetre
MCB	:	Miniature Circuit Breaker
BOPP	:	Biaxially Oriented Polypropylene
RPM	:	Revolution per Minute
A	:	Adjustable
SS	:	Stainless Steel
HP	:	Horse Power
AMP	:	Ampere
STD	:	Standard
BTM	:	BOPP Taping Machine
V	:	Volt
Hz	:	Hertz



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17.0 POST 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)			