



# **INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR PACKING CONVEYOR**

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>Packing Hall</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES PROTOCOL No.</b>	<b>NIL</b>



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR PACKING CONVEYOR**

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**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR PACKING CONVEYOR**

**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)			



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR PACKING CONVEYOR**

**2.0 OBJECTIVE:**

- To carry out the Installation Qualification of Packing Conveyor to online operation/transfer of vials from one area to another or from one machine to another.
- 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 **Packing Conveyor (Make: .....)**.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required for installation qualification activity.



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR PACKING CONVEYOR**

**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:

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



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR PACKING CONVEYOR**

**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Packing Conveyor
<b>Equipment</b>	
<b>Manufacturer's Name</b>	Punchtab Engineering Private Limited
<b>Supplier's Name</b>	Punchtab Engineering Private Limited
<b>Location of Installation</b>	Packing Hall

**6.0 SYSTEM DESCRIPTION:**

Packing Conveyor is suitable for online operation/transfer of packing material from one area to another or from one machine to another. Packing Conveyor can also be used to adjust the packing area length with other machines. Packing conveyor is suitable for easy movement of material or operator.

The conveyor system is available in various speed ranges with option of fixed speed or variable speed drive system using AC Variable frequency drive system.

The conveyor belt brings the container or products from the labeling/ blister/ strip machine, operator in turn pickup. These bottles/ products & visually inspect the bottles/ products & doing necessary action like primary packing, secondary packing, picking & placing at proper place.



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR PACKING CONVEYOR**

**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.



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR PACKING CONVEYOR**

**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 Packing Conveyor.		
2.	Check the proper electrical installation of Packing Conveyor		
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: .....**





**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR PACKING CONVEYOR**

**8.2 General Checks and Location Suitability:**

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



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR PACKING CONVEYOR**

**8.3 Installation Checks:**

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
<b>Overall Dimension</b>	3060 (L) mm X 866 (W) mm X 800 (H) mm		
<b>Conveyor Dimension</b>	3050 (L) mm X 280 (W) mm		
<b>Direction of Movement</b>	Left to Right		
<b>Main Motor</b>	Make : Bonfiglioli Riduttori Type : 03 Phase Induction Motor Sr. No. : 797225 Code : 830720106 Electric Supply : 50 Hz, 0.37 kW, 1.82-1.05 A, 1370 RPM. Electric Supply : 60 Hz, 0.45 kW, 1.09 A, 1660 RPM.		
<b>Gear Box</b>	Make : Bonfiglioli Group Type : VF49F1P71B5 Code : 1177654+797225		
<b>ON/OFF Push Botton</b>	ON : Green OFF : Red Make : "BENTEX"		

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

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

**Inference:**

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



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR PACKING CONVEYOR**

**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.	Conveyor	Delrin		
4.	Machine Frame	SS 304		

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

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

**Inference:**

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



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR PACKING CONVEYOR**

**8.5 Safety:**

Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Well embedded equipment	For Packing Conveyor.		
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  
(Production)  
Sign/Date: .....**

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

**Inference:**

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



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR PACKING CONVEYOR**

**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.





**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR PACKING CONVEYOR**

**14.0 CONCLUSION:**

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**15.0 RECOMMENDATION:**

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**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR PACKING CONVEYOR**

**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
RPM	:	Revolution per Minute
SS	:	Stainless Steel
HP	:	Horse Power
AMP	:	Ampere
STD	:	Standard





**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR PACKING CONVEYOR**

**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)			