



**PHARMA DEVILS**

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

**PROTOCOL No.:**

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

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>Vial Filling &amp; Stoppering Room</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES PROTOCOL No.</b>	<b>NIL</b>



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**1.0 PRE – APPROVAL:**

**INITIATED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (PRODUCTION)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (QUALITY ASSURANCE)</b>			



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**2.0 OBJECTIVE:**

- To carry out the Installation Qualification of Swing 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 **Swing Conveyor (Make: Punchtab Engineering Private Limited)** to be installed between Vial Filling & Stoppering Machine and Vial Sealing Machine.
- 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:

<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><li>• Post Approval of Qualification Protocol cum Report after Execution.</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 Swing 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>



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**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Swing Conveyor
<b>Equipment</b>	
<b>Manufacturer's Name</b>	
<b>Model</b>	cGMP Model
<b>Supplier's Name</b>	
<b>Location of Installation</b>	Vial Filling & Stoppering Room

**6.0 SYSTEM DESCRIPTION:**

Swing Conveyor used for transfer of filled & Stoppard vials from filling & stoppering machine to vial sealing machine.

The Conveyor system is available with adjustable speed from (1-60). Digital display is provided for VFD.



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





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**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>	Vial Filling & Stoppering Room		
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:** .....



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**8.3 Installation Checks:**

<b>Critical Variables</b>	<b>Acceptance Criteria</b>	<b>Observation</b>	<b>Observed By (Engineering) Sign/Date</b>
<b>Equipment</b>	Swing Conveyor		
<b>Overall Dimensions</b>	1100 (L) mm X 396 (W) mm X 1078 (H) mm		
<b>Conveyor Dimensions</b>	990 (L) mm X 100 (W) mm		
<b>Main Motor &amp; Gear Box for Conveyor</b>	Make : Bonfiglioli Riduttori Electric Supply : 50 Hz, 380- 415 V, 0.72-0.74 A Electric Supply : 60 Hz, 440- 480 V, 0.68-0.71 A		
<b>ON/OFF Push Botton</b>	Make : "ESBEE"		
<b>Digital Display for VFD</b>	Make : Allen Bradley (Power Flex 4 M) Speed : 1-60 (Adjustable) Motor Rating: 0.4 kW/0.5 HP Input Supply: 01 Phase, 200-240 V, 48-63 Hz. Ampere: 6.5 AC Voltage Range: 180-264 Output Supply: 03 Phase, Ampere: 2.5 AC Voltage Range: 0-230 V		
<b>Indicators</b>	Nos. : 02 Type : Led Indicators Volt : 240 V, AC Supply		



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<b>Critical Variables</b>	<b>Acceptance Criteria</b>	<b>Observation</b>	<b>Observed By (Engineering) Sign/Date</b>
<b>Castor Wheel with Interlockings</b>	Nos. : 02		
<b>MCB</b>	Make : L & T Type : C 16 Volt : 240/415 V		

**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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**8.4 MOC Verification List:**

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

**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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**8.5 Safety:**

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



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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
MOC	:	Material of construction
cGMP	:	Current Good Manufacturing Practices
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
L	:	Length
W	:	Width
H	:	Height



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**17.0 POST APPROVAL:**

**INITIATED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (PRODUCTION)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (QUALITY ASSURANCE)</b>			