



PHARMA DEVILS

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

PROTOCOL No.:

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

EQUIPMENT ID. No.	
LOCATION	Vial Filling & Stoppering Room
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 verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Swing Conveyor and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this Operational Qualification Protocol Cum Report is limited to qualification of **Swing Conveyor (Make: Punchtab Engineering Private Limited)** installed between Vial Filling & Stoppering Machine and Vial Sealing Machine.
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of Swing Conveyor.
- Successful completion of this Protocol cum Report will verify that Swing Conveyor meet all acceptance criteria and ready for Production Use.



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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">• Preparation, Review, Approval and compilation of the operational Qualification Protocol cum Report.• Co-ordination with Production and Engineering to carryout Operational Qualification.• Monitoring of Operation Process.• Post Approval of Operational Qualification Protocol cum Report after Execution.
Production	<ul style="list-style-type: none">• Review of Operational Qualification Protocol cum Report.• To Co-ordinate and support for execution of Operational Qualification study as per Protocol.• Post Approval of Operational Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review of Operational Qualification.• To co-ordinate and support Operational Qualification Activity.• Calibration of Process Instruments.• Post Approval of Operational Qualification Protocol cum Report after Execution.



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5.0 EQUIPMENT DETAILS:

Equipment Name	Swing Conveyor
Equipment	
Manufacturer's Name	Punchtab Engineering Private Limited
Model	cGMP Model
Supplier's Name	Punchtab Engineering Private Limited
Location of Installation	Vial Capping Room

6.0 EQUIPEMENT 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:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- Draft SOP for Operation & Cleaning of Swing Conveyor.
- Draft SOP for Preventive Maintenance of Swing Conveyor.
- Electrical Circuits Diagram.
- Technical specification of equipment.

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 OQ 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 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents.

Any deviations or issues should be rectified and documented prior to OQ commencing.

S. No.	Document Name	Document / SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (Quality Assurance) Sign/Date
1.	DQ Protocol cum Report				
2.	IQ Protocol cum Report				
3.	Draft SOP for Operation & Cleaning of Swing Conveyor.				
4.	Draft SOP for Preventive Maintenance of Swing Conveyor.				

**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 Test Equipment Calibration:

Verify that all critical instruments associated with the system are in a calibrated state. Review the calibration status for the test equipment to be utilised and record the calibration due dates in the table below. All Equipment/Instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

Equipment/ Instruments Name	Equipment/Instrument I.D.	Calibration On	Due On	Observed By Sign/Date

**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 Operational and Functional Checks:

Operate the Swing Conveyor as per Manufacturer’s Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

Item	Operation	Acceptance criteria	Observation
Power supply	Connect 3Phase, 415V, AC supply to the panel through proper isolation.	Machine will be ready for operation.	
Motor & drive	Check the direction of motor shows on machine by direction arrow.	Motor should not run in opposite direction as arrow shows.	
Conveyor Speed Adjustor	Run the Conveyor at different speed.	Motor can be allowed to run at adjustable speed.	
Earthing	Proper earthing should be provided to machine.	Earthing will secure from shocks to operator of machine.	
Castor Wheel with Interlockings	For easy shifting of the machine.	Smooth handling & easy handling can be done.	

**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 Power Failure Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

**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 Emergency Operation Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
ON/OFF Push Button <ul style="list-style-type: none"> • Press ON Button • Press OFF Button 	<ul style="list-style-type: none"> • Equipment should Start • Equipment should Stop 		
With the Press OFF Button pressed, try to cause movement of an operating function.	The Equipment will be inoperative.		

**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:

- Operation and Maintenance Manual.
- Copy of Draft SOPs.
- Any other Relevant Documents.



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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
cGMP	:	Current Good Manufacturing Practices
mm	:	Millimetre
Amp.	:	Ampere
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
MOC	:	Material of Construction
NLT	:	Not Less Than
HP	:	Horse Power
KW	:	Kilo Watt
SS	:	Stainless Steel
ID.	:	Identification
Kg	:	Kilo Gram
AC	:	Alternating Current
CON	:	Conveyor
Ltrs	:	Liters
MCB	:	Miniature Circuit Break



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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)			