



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR ONLINE VISUAL
INSPECTION CONVEYER**

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
ONLINE VISUAL INSPECTION
CONVEYER**

EQUIPMENT ID. No.	
LOCATION	Packing Hall
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	NIL



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR ONLINE VISUAL
INSPECTION CONVEYER**

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PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR ONLINE VISUAL INSPECTION CONVEYER

1.0 PRTOCOL PRE-APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR ONLINE VISUAL INSPECTION CONVEYER

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Online Visual Inspection Conveyer.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of **Online Visual Inspection Conveyer (Make –)** to be installed in the Packing Hall.
- The Online Visual Inspection Conveyer is a standalone unit with plug in type electrical connections for operation and is on castor wheel. Hence, may be moved as per requirement to other area of operation which shall not change the performance of equipment.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Online Visual Inspection Conveyer.



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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, Authorization, Review 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">• 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 of Protocol cum Report.• Co-ordination, Execution and technical support in vibro-sifter Qualification Activity.• Calibration of Process Instruments.• Responsible for Trouble Shooting (if occurs during execution).• Review of Qualification Protocol cum Report after Execution



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5.0 EQUIPMENT DETAILS:

Equipment Name	Online Visual Inspection Conveyor
Equipment	
Machine Sr. No.	
Manufacturer's Name	
Model	
Supplier's Name	
Location of Installation	Packing Hall

6.0 SYSTEM DESCRIPTION:

The purpose of the **Online Visual Inspection Conveyor 15 Feet (Model:)** is to convey & inspect the specific size and shape of IV Bottle at the variable speed according to requirement of feeding to the next unit.

Complete machine can be divided in following sub sections.

MAIN ASSEMBLY:

1. Structure of Machine
2. Mechanism of drive unit with selector switch operating panel
3. Conveyor belt and platform
4. Inspection booth with both side black & white radium film



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7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document
- Electrical circuits diagram
- Technical specification of equipment
- Certificate of material of construction of components.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 General Checks and Location Suitability:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION COMPLIES/NOT COMPLIES	OBSERVED BY (ENGINEERING) SIGN/DATE
Leveling	Should be properly balanced and leveled		
Edges of parts	Metal parts should be properly grind without any sharp edges		
Welding of Joints	Welding of joints should be without any welding burrs		
Place of Installation	Packing Hall		
Room Condition	General working condition		
Illumination in area	NLT 300 Lux.		
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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8.2 Equipment Verification:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION Complies/Not Complies	OBSERVED BY (ENGINEERING) SIGN/DATE
ELECTRICAL INSTALLATION:			
Electricity	Voltage	415 V	
	Phases	3 Phase	
	Frequency	50 Hz	
Electrical connections have been provided and secured.	Should be provided & secured		
All components in the panel are properly secured	Should be properly secured		
All terminals are tightened	Should be tightened		
MECHANICAL INSTALLATION			
Check that all parts are getting lubricated	All parts should be lubricated		
Earthing connection to control panel & equipment	Earthing connection to control panel & equipment should be provided.		
The machine cleaning	The machine should clean.		
Visually check the M/C for damage due to transportation.	M/C should be free for damage due to transportation.		

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Production
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8.3 MOC Verification List:

COMPONENT	MOC	OBSERVATION Complies/Not Complies	OBSERVED BY (ENGINEERING) SIGN/DATE
Conveyor Belt	Endless Rubberized Belt		
Drive Shaft	MS		
Platform	SS 304		
All Nuts and Bolts	SS 304		
Panel Box	SS 304		
Inspection Booth	SS 304 with Black & White Radium Film		
Legs Bolt & Pad	SS 304 with UHMW Ring		

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8.4 Technical Detail Verification:

S. No.	NAME OF COMPONENTS	ACCEPTANCE CRITERIA	OBSERVATION Complies/Not Complies	OBSERVED BY (ENGINEERING) SIGN/DATE
1.	Material of construction	SS-304, MATT FINISH		
2.	External size	4575 mm (L) x 925 mm (W) x 1566 ± 50 mm (H)		
3.	Working size	850 ± 50mm		
4.	Weight	150 kg Approx.		
5.	Power supply	1 Phase, 230 V, 50 Hz		
6.	Electric Motor : 01 Nos.	Make : Rotomotive Type : 3 Phase Squirrel cage induction motor (71B - 4) RPM : 1350 KW/HP : 0.37 / 0.5 Sr. No. :M05171021		
7.	Gear Box – 01 Nos.	Make : Rotomotive PAM : 71B5 I : 20:1 M. Type : BOX 040 Sr. No : G05170968		
8.	Variable Frequency Drive – 01 Nos.	Make : Delta Model : VFD004L21A KW/HP : 0.4/ 0.5 I/P Supply : 1 Phase,6.5A/3PH 2.7A 200-240V, 50-60 HZ O/P Supply : 3Phase, 0 - 240 V, 2.5A, 0.4KVA Sr. No. 004L21A6W17111190		
9.	Pot – 01	Make : Pankaj		



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S. No.	NAME OF COMPONENTS	ACCEPTANCE CRITERIA	OBSERVATION Complies/Not Complies	OBSERVED BY (ENGINEERING) SIGN/DATE
	Nos.	Model : RW-3 Range : 10 KΩ		
10.	ON/OFF Switch – 01 Nos.	Make : Salzer Type : 3 Pole, 6 – Amp., 440V AC		
11.	Conveyor Belt – 01 Nos.	Size : 9040 X 455 X 2.1mm MOC : Rubberized Endless PVC Belt		
12.	Legs Pad – 06 Nos.	Size: 78 mm Dia. MOC : SS 304 & UHMW Ring		
13.	Legs Bolt – 06 Nos.	Size: 180mm Length. MOC : SS304		
14.	Tube Light- 08Nos.	Make : Local Rating : 40W, 0.4 Amp I/P Supply : 1 Phase, 230 V AC, 50HZ		

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8.5 Safety:

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION Complies/Not Complies	OBSERVED BY ENGINEERING SIGN/DATE
Well embedded equipment	For proper sifting		
Electrical wiring and Earthing	Electrical wiring should be as per approved drawings. Double external earthing to control machine (motors).		
Guards	Guards for all moving parts		
	Should be provided For Motor safety		
Start On/Off switch: To stop the process immediately	Should be provided For equipment and operator safety		

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Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:



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9.0 REFERENCES:

- Validation Master Plan
- Design Qualification protocol cum Report
- P & ID, GA Drawing and Schematic Layout
- 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
- Component certificate

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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12.0 CHANGE CONTROL, IF ANY:

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

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

- Amp. : Ampere
- cGEP : Current Good Engineering Practices
- cGMP : Current Good Manufacturing Practices
- HP : Horse power
- ID. : Identification
- IQ : Installation Qualification
- Kg : Kilo gram
- KW : Kilo watt
- MCB : Miniature Circuit Break
- mm : Mili meter
- MOC : Material of construction
- NLT : Not less than
- No. : Number
- SS : Stainless Steel
- WHO : World Health Organization



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17.0 PROTOCOL POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER / EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			