INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIAL OPTICAL INSPECTION MACHINE

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

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIAL OPTICAL INSPECTION MACHINE	PROTOCOL No.:

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PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIAL OPTICAL INSPECTION MACHINE	PROTOCOL No.:

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)			

2.0 OBJECTIVE:

- To carry out the Installation Qualification of Vial Optical Inspection Machine to be used for inspection of vial contains any foreign particles, broken vial or not properly sealed vial.
- 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 **Vial Optical Inspection Machine (Make: ……..)** to be installed in the **Packing Hall**.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required for installation qualification activity.

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	• 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. • Post Approval of Qualification Protocol cum Report after Execution.
Production	• 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	• Review & Pre Approval of Protocol cum Report. • Co-ordination, Execution and technical support in Vial Optical Inspection 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.

5.0 EQUIPMENT DETAILS:

Equipment Name	Vial Optical Inspection Machine
Equipment	……..
Manufacturer's Name	Ambica Pharma Machines Private Limited
Model	AVIN - 240
Supplier's Name	Ambica Pharma Machines Private Limited
Location of Installation	Packing Hall

6.0 SYSTEM DESCRIPTION:

In Vial Optical Inspection Machine, an operator can check/inspect whether the vial contains any foreign particles, broken vial or not properly sealed vial, with the help of speed adjustment provision, spin rotation of vial, mirror & magnifying glass. The working of this machine is very simple. Normally this process is done once the vial is filled and sealed.

From the Unscrambler with the help of the guides the vials move to the Nylon Chain Roller. These rollers are responsible for the movement of the vials. On the backside of the conveyor glass mirrors are fixed so that the operators can visually check the vial without hand touch. This machine is suitable for four operators, two operators on each side. Each operator has been provided with his or her inspection section. It means that each operator has separate inspection area in which they have to do the inspection. The inspection area is illuminated with the help of tube light, which is fitted on the top of the inspection hood on the inner side.

The rollers move round which in turns the vial round so that the operator can see from every side. The operator has to see the same on the mirror which is fitted on the back side of the conveyor. Then it moves towards. During the inspection, if the operator finds that one of the vial is not properly sealed or some particles are mixed up with the powder then the same is to be picked up from the roller and drop it to the rejection box. After the inspection is over it moves for the vial labeling section.

Vial Optical Inspection Machine is equipped with SS square frame Turn Table and is useful to ensure total synchronization, uniform flow of vial. Vial inputs in turn table by manually or automatic will rotate on disk of turn table and exit through a SS strip, will guide the container towards outlet path.

7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Technical Specification of Equipment.
- Calibration Certificate 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.

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7.1.2 Acceptance Criteria:

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

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 Vial Optical Inspection Machine.		
2.	Check the proper electrical installation of Vial Optical Inspection Machine.		
3.	Check the parts are working properly.		
4.	Check the equipment is free from any defects.		
5.	Check the finishing of product contact parts.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIAL OPTICAL INSPECTION MACHINE	PROTOCOL No.:

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.	**Tube Light Illumination**	NLT 2200 Lux (Should be sufficient for easy operation).		
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: ……

8.3 Installation Checks:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Equipment	Vial Optical Inspection Machine		
Model	AVIN - 240		
Output	0-240 Vials per Minute		
Dimension	3360 (L) mm X 1100 (W) mm X 835 ± 50 (H) mm		
Conveyer Height	As per Line Height		
Main Motor & Gear box	Nos. : 02 (01 No. Left & 01 No. Right)		
Tube light Frame	Make : Havells Nos. : 04 (02 Nos. Left & 02 Nos. Right)		
Magnifying Glass	Nos. : 04 (02 Nos. Left & 02 Nos. Right)		
Mirror	Nos. : 04 (02 Nos. Left & 02 Nos. Right)		
Main Electrical Supply Switch (Tube Light ON/OFF Switch)	Nos. : 02 (01 No. Left & 01 No. Right)		
Conveyer ON/OFF Switch	On Switch (Green Push Button) Nos. : 02 (01 No. Left & 01 No. Right) OFF Switch (Red Push Button) Nos. : 02 (01 No. Left & 01 No. Right)		
Turn Table ON/OFF Switch	Nos. : 02 (01 No. Left & 01 No. Right)		

 PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIAL OPTICAL INSPECTION MACHINE	PROTOCOL No.:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Motor & Gear Box for Conveyer	**Motor & Gear Box for Conveyer (Left)** Make : Bonfiglioli Riduttori S. No. : 71596220310 Electric Supply : 50 Hz, 380- 415 V, 0.72-0.74 A Electric Supply : 60 Hz, 440- 480 V, 0.68-0.71 A **Motor & Gear Box for Conveyer (Right)** Make : Bonfiglioli Riduttori S. No. : 71596220318 Electric Supply : 50 Hz, 380- 415 V, 0.72-0.74 A Electric Supply : 60 Hz, 440- 480 V, 0.68-0.71 A **Motor & Gear Box for Turn Table** Nos. : 02 Make : Bonfiglioli		
VFD	Nos. : 04 (02 Nos. Left & 02 Nos. Right) (Left 1st for Conveyer & Left 2nd for Turn Table). (Right 1st for Turn Table & Right 2nd for Conveyer). Speed : 01-50 RPM		

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIAL OPTICAL INSPECTION MACHINE	PROTOCOL No.:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Digital Display for VFD	Make : Delta Nos. : 04 (Left 1st for Conveyer & Left 2nd for Turn Table). (Right 1st for Turn Table & Right 2nd for Conveyer). Electric Supply : 50 Hz, 01 Phase, 230 V, 0.4 kW		
Turn Table	Make : Ambica Pharma Machines Private Limited Nos. : 02 Direction of Rotation: Clockwise/ Anti clockwise (As per requirement). Electric Supply: 50 Hz, 03 Phase, 415 V, 0.5 HP		
Chain Sprockets	Make : Mild Steel duly Zinc Plated.		
Chain	Make : Rolon		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.4 MOC Verification List:

S.No.	Parts Name	Material of construction	Observation	Observed By (Engineering) Sign/Date
1.	**Rollers**	Nylon		
2.	**Roller Pin**	SS 316		
3.	**Doors & Covers**	SS 316		
4.	**Chain Covers**	SS 304		
5.	**Main Hood**	SS 304		
6.	**Conveyer Plates**	SS 304		
7.	**Conveyer Shafts**	SS 304		
8.	**Conveyer Collars**	SS 304		
9.	**Machine Frame**	SS 304 Square pipe frame Structure		
10.	**Inverter Channels**	Delrin		
11.	**Turn Table Plate**	Aluminium Casting duly cladded by SS Sheet.		
12.	**All Gide Plates**	SS 304		
13.	**Shafts**	M.S. Zinc Plated		
14.	**Covers**	SS 304		
15.	**Magnifying Glass**	Fiber		
16.	**Turn Table**	SS 304		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.5 SAFETY:

Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Well embedded equipment	For Vial Optical Inspection Machine.		
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 Motor 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: ……

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:

- Any other relevant documents.

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:

No.	:	Number
WHO	:	World Health Organization
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
kW	:	Kilo Watt
V	:	Volt
Hz	:	Hertz
NLT	:	Not Less Than
VOI	:	Vial Optical Inspection Machine

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)			