OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR VIAL OPTICAL INSPECTION MACHINE

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

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

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 PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR VIAL OPTICAL INSPECTION	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 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 Vial Optical Inspection Machine 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 **Vial Optical Inspection Machine (Make: Ambica Pharma Machines Private Limited)** to be installed in the **Packing Hall.**
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of Vial Optical Inspection Machine.
- Successful completion of this Protocol will verify that Vial Optical Inspection Machine meet all acceptance criteria and ready for Production Use.

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	• 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	• 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	• 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.

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 EQUIPEMENT 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:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- SOP for Operation & Cleaning of Vial Optical Inspection Machine.
- 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.

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 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	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.	SOP for Operation & Cleaning of Vial Optical Inspection Machine.			

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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: ……

8.3 Operational and Functional Checks:

Operate the Vial Optical Inspection Machine as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

Component	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Start Green Push Button	Conveyer Start		
Stop Red Push Button	Conveyer Stop		
Earthing	Proper earthing should be provided to machine.		
Leveling of equipment. (Place the spirit level indicator at different points on the machine frame).	The air bubble of the spirit level indicator should be observed in the center.		
Tube Light Illumination	NLT 2200 Lux (Should be sufficient for easy operation).		
Conveyor Belt Speed Controller Knob • Rotate the knob in Clock wise direction. • Rotate the knob in Anti clock wise direction.	• Conveyor belt speed should be decreased. • Conveyor belt speed should be increased.		
Direction of Rotation of Turn Table	Clockwise/ Anti clockwise (As per requirement).		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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: ……

8.5 Emergency Operation Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
ON/OFF Push button • Press Stop Push Button • Press Start Push Button	Equipment should Stop		
	Equipment should Start		
With the ON/OFF Push Button Pressed in, in 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: ……

9.0 REFERENCES:

The Principle Reference is the following:

- 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 PREDEFINED 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
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
MOC	:	Material of Construction
ID.	:	Identification
MCB	:	Miniature Circuit Break
SOP	:	Standard Operating Procedure
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)			