PERFORMANCE QUALIFICATION PROTOCOL FOR VIAL OPTICAL INSPECTION MACHINE

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

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR VIAL OPTICAL INSPECTION MACHINE	PROTOCOL No.:

PROTOCOL CONTENTS

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR VIAL OPTICAL INSPECTION MACHINE	PROTOCOL No.:

1.0 PROTOCOL 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 provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all test parameters meet the pre-defined acceptance criteria.

3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for the **Vial Optical Inspection Machine,** installed in the Packing Hall.
- This Protocol will define the methods and documentation used to qualify The Vial Optical Inspection Machine for PQ.

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.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Approval and Compilation of the Performance Qualification. • Protocol Training. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review of Protocol. • To co-ordinate and support Performance Qualification Activity.
Engineering	• Reviewing of qualification protocol for correctness, completeness and technical excellence. • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule.

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 REASON FOR QUALIFICATION:

- New equipment in Packing Hall.
- After completion of the Operation Qualification of the Equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

8.0 SITE OF STUDY:

Packing Hall.

9.0 FREQUENCY OF QUALIFICATION:

- Once in a five year ± one month.
- After any major breakdown or after major modification.
- After Change of Location.

10.0 PRE – QUALIFICATION REQUIREMENTS:

The below mentioned activities should be completed prior to commencing the performance qualification activity:

- Design Qualification.
- Installation Qualification.
- Operational Qualification.
- Calibration of all critical Components of Equipment.
- Preparation of SOP for Operation & Cleaning of Vial Optical Inspection Machine

11.0 TESTS AND CHECKS:

11.1 Evaluation of Performance:

11.1.1 Objective:

To evaluate and to provide documented evidences for performance of equipment for proper visual of filled vials. The objective of the test is to determine the Speed & Lux Level whether the visual inspector are able to easily identify the rejection.

11.1.2 Checks for machine:

- Verification of Machine Speed.
- Lux Level
- Challenge Test

11.1.3 Test & Method:

- The Equipment shall be checked for its performance attributes for all pack size vials.
- 1000 Vials are taken in from each size of pack & three cycles at Low, Optimum and High speed for verification of Sealing Quality and Sealing speed.

11.1.4 Acceptance Criteria:

- No. of Vials should be as per defined speed.
- Lux Level should be NLT 2200.
- During Challenge test all rejection should be easily find out.

12.0 CHECKLIST OF ALL TESTS & CHECKS:

A checklist shall be provided to ensure that all tests or checks required for this protocol have been executed. After execution observations shall be recorded in Performance Qualification Report.

The list includes:

- Verification of DQ, IQ & OQ & other documents.
- Verification of visual machine performance.

13.0 REFERENCES:

The Principle References are as 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.

14.0 DOCUMENTS TO BE ATTACHED:

- Any other relevant document.

15.0 NON COMPLIANCE:

All the Non-compliances of procedure, specifications, and sampling, analysis and documentation activities shall be monitored & recorded.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an

  Impact on operation as well as on performance of the machine & prepare final conclusion.

17.0 CHANGE CONTROL, IF ANY:

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

18.0 ABBREVIATIONS:

WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
EU	:	European Union
CQA	:	Corporate Quality Assurance
QC	:	Quality Control
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
SOP	:	Standard Operating Procedure
NLT	:	Not Less Than
KW	:	Kilo watt
SS	:	Stainless Steel
ID.	:	Identification
mm	:	Mili meter
MCB	:	Miniature Circuit Breaker
ID	:	Inner Diameter