OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR VIAL FILLING & STOPPERING MACHINE

EQUIPMENT ID. No.	
LOCATION	**Vial Filling & Stoppering Room**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR VIAL FILLING & STOPPERING MACHINE	PROTOCOL No.:

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PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR VIAL FILLING & STOPPERING 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 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 Filling & Stoppering 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 Filling & Stoppering Machine (Make: Amba Sale & Services.)** installed in the Vial Filling & Stoppering Room.
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of Vial Filling & Stoppering Machine.
- Successful completion of this Protocol will verify that Vial Filling & Stoppering Machine meet all acceptance criteria and ready for Performance Qualification.

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 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 after Execution.
Engineering	• Review of Operational Qualification. • To co-ordinate and support Operational Qualification Activity. • Calibration of Process Instruments. • Post Approval of Qualification Protocol cum Report after Execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	Vial Filling & Stoppering Machine
Equipment ID.	……..
Manufacturer's Name	Amba Sale & Services
Supplier's Name	Amba Sale & Services
Location of Installation	Vial Filling & Stoppering Room

6.0 EQUIPEMENT DESCRIPTION:

The equipment is an automated means to fill sterile dry powder with different weights in different sizes of vials & rubber stoppered the same as well pressing of rubber stopper vial. The equipment having four heads with double track filling action. This machine works on vacuum filling principle giving guarantee of high accuracy of fill weight with minimal spillage.

Sterile dry powder loads into powder hopper. Powder hopper will agitate the powder & delivers to the port wheel through powder agitator .When wheel port come under the powder hopper, vacuum will take place.

Powder hopper agitator will push down the powder & due to vacuum in.

Wheel port, powder will enter into the port & fills in it. As soon as wheels start rotating, Doctor Blades will scrap out the excess powder from wheel.

An electro mechanical sensor will sense the presence of vial & pass signal to the solenoid valve. Once powder slug purge into vial, vial separators will carry the vial & pass on the same conveyor belt for the rubber Stoppering process.

Filled vials convey on slat conveyor belt for next operation, as soon as filled vial comes to the lateral belt, same will hold the vial firmly from body diameter & will carry vial underneath the rubber stopper chute, the filled vial will pick one rubber stopper from rubber stopper chute & belt will carry the same vial for pressing the rubber stopper under the two pressing roller.

The first roller will position the rubber stopper & second will press the rubber stopper. Still lateral belts are holding the vial after pressing the rubber stopper, lateral belt will push out the vial on conveyor & conveyor will transfer the vial on scrambler turn table for next Operation.

7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- Draft SOP for Operation & Cleaning of Vial Filling & Stoppering Machine.
- Draft SOP for Preventive Maintenance of Vial Filling & Stoppering Machine.
- 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.

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 Vial Filling & Stoppering Machine.				
4.	Draft SOP for Preventive Maintenance Vial Filling & Stoppering 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 Filling & Stoppering Machine as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

Test to be carried out & Procedure	Activity Specification	Observation	Observed By (Engineering) Sign/Date
Start & Stop Switch			
Press Start Switch	Machine should started by pressing the green switch on push button.		
Press Stop Switch	Machine should stop by pressing the Red switch on push button.		
Main Motor Functionality			
Start Motor	Powder filling unit Should Run		
Stop Motor	Powder filling unit Should Stop		
Variable Frequency Drive functionality			
Check the functionality of Variable Frequency Drive.	Frequency of input current to motor in Hz		
Conveyor Belt			
Start Conveyor Belt	Conveyor belt should run without Jerk		
Stop Conveyor Belt	Conveyor belt should Stop.		
Unscramble Table functionality			
Switch on Unscrambler table Motor	Unscramble table should run without Jerk		
Switch off Unscrambler table Motor	Unscrambler table should stop.		
Scrambler Table functionality			
Switch on scrambler table Motor	Scrambler table should run without Jerk		

Switch off scrambler table Motor	Scrambler table should stop.		
Powder Hoppers Vibrators functionality			
Switch on Powder Hoppers Vibrators	Vibrators should vibrate the hopers uniformly		
Switch off Powder Hoppers Vibrators	Vibrators should stop.		
Rubber Stopper Bowl Vibrators functionality	Vibrator should vibrate the hopers uniformly & also check delivery of rubber stoppers to vial through rubber stopper chute.		
Rubber Stopper Pressing Device Assembly	Pressing Roller should working properly & press Rubber Stoppers Effectively		
No Vial No Filling proximity	If there is no vial below powder wheel than there should no filling of Powder.		
Air Regulator for Nitrogen & Compressed Air	Air Pressure should increase & Decrease through Air & Nitrogen Regulator.		

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 • Release ON Push Button	Equipment should Stop		
	Equipment should Start		
With the Emergency Stop 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:

- 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.

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
SOP	:	Standard Operating Procedure
MOC	:	Material of Construction
SS	:	Stain less Steel
VFS	:	Vial Filling & Stoppering Machine
ID	:	Inner Diameter

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)			