INSTALLATION 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	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIAL FILLING & STOPPERING MACHINE	PROTOCOL No.:

CONTENTS

PHARMA DEVILS	INSTALLATION 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 provide documented evidence for the Installation Qualification of Vial Filling & Stoppering Machine.
- 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 **Vial Filling & Stoppering Machine (Make: ……..)** to be installed in the **Vial Filling & Stoppering Room**.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Vial Filling & Stoppering Machine.

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 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 after Execution.
Engineering	• Review & Pre Approval of Protocol cum Report. • Co-ordination, Execution and technical support in VFS Installation Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Qualification Protocol after Execution.

5.0 EQUIPMENT DETAILS:

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

6.0 SYSTEM 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:

- Executed and approved design qualification document.
- Piping and instrumentation diagram (P& ID).
- Electrical circuits diagram.
- Technical specification of equipment.
- Calibration certificate of components.
- Certificate of material of construction 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.
- Approved Drawings and supporting documents would form a part of the IQ 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 Installation Qualification Checklist:

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Grouting and Mounting	Should be properly grouted and mounted.		
Leveling	Should be properly balanced and leveled.		
Edges of parts	Metal parts should be properly ground without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	Vial Filling & Stoppering Room		
Room Condition	RH : NMT 30% TEMP : 23 ± 2 ºC		
Illumination	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: ……

8.2 Installation Checks:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Model	AHPF - 250		
Dimensions	3168 mm x 1804mm x 770 mm		
Main drive assembly	**Motor** Make : Remi Power : 0.75 kw RPM : 1390 RPM HZ : 50 Hz **Gear box** Make : Bonfiglioli Power : 0.75 kw RPM : 1390 RPM		
Conveyor belt	Quantity : 1 Nos.		
Filling head assembly	Quantity : 1 Nos.		
Unscrambler & scrambler turn table	**Motor** Make : Remi Power : 0.25 HP		
Powder Hopper	Quantity : 1 Nos.		
Port Wheel	Quantity : 1 Nos.		
Vial separator assembly or Carriage assembly	Quantity : 1 Nos.		
Rubber stopper bowl	Quantity : 1 Nos.		
Lateral belt	Quantity : 1 Nos.		
Vibrator assembly	Quantity : 1 Nos.		
Rubber stopper pressing device assembly	Quantity : 1 Nos. Make : Chain Drive		
Vial holding pressing device assembly	Quantity : 1 Nos.		

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

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
On / Off Main switch	Make : Wago Quantity : 1 Nos. 16 Amp. , 2 Pole		
Indicating Lamp	Make : Technique Quantity : 1 Nos. 220 VAC		
Sensor	Make : Accent Quantity : 1 Nos. Inductive Proximity		
MCB	Make : Indo Kopp Quantity : 1 Nos. 6 Amp. , 2Pole		
Power Relay	Make : PLA Quantity : 1 Nos. 230VAC, 5 Amp		
Vibrator Card	Make : Amba Quantity : 1 Nos.		
AC Drive Turn Table	Make : Delta Quantity : 1 Nos. 0.5 HP, 220V AC,1 Phase		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.3 MOC Verification List:

Parts Name	Material of construction	Observation	Observed By (Engineering) Sign/Date
Filling Head Assembly	S.S. 304		
Unscrambler & Scrambler Turn Table	S.S. 304		
Powder Hopper	S.S. 316 L		
Port Wheel	S.S. 316 L		
Rubber Stopper Bowl	S.S. 316 L		
Vibrator Assembly	S.S. 316 L		
Conveyor Guide Rail	S.S. 304		
Conveyor 'C' Channel	S.S. 304		
Universal Joint (for Powder Hopper)	Carbon steel duly cladded with S.S		
Filling Head & Rubber Stopper Pipe	S.S. 304		
Pipe Housing	S.S. 304		
Rubber Stopper Pressing Roller	S.S. 304		
Vial holding Pressing Device Block	S.S. 304		
Vibrator Bowl	S.S. 316 L		
Vibrator Bowl Chute	S.S. 316 L		
Powder Wheel Piston	S.S. 316 L		
Doctor Blade for Hopper	S.S. 316 L		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.4 Utility Verification List:

Critical variables	Acceptance criteria	Observation	Observed By (Engineering) Sign/Date
Electrical Supply	Voltage : 220 V Phase : 1 Phase Frequency : 50 HZ		
Room Condition	Temperature : 23 ± 2 ºC RH : NMT 30 %		
Air supply(Nitrogen gas for dosing)	1 Kg/cm^2		
Vacuum supply	25 Hg.		

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:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Hardware Emergency switch at Operator Console	For Operator Safety.		
Vacuum pressure drop interlock	For safety of the batch		
Powder low level – Machine stop	For safety of the batch & the process.		
Rubber stopper low level – Machine stop	For safety of the batch & the process.		
Motor overload Relay	For Motor & equipment protection.		
Air Regulator for Nitrogen & Compressed Air	Control the velocity of Nitrogen & Compressed air		
No Vial No Filling Sensor	To avoid the wastage of product.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.5.1 Control Panel Check:

Test Particulars	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Check that Machine is connected with control panel. Record the details of PLC	Machine should be connected with control panel. PLC make, model no. , serial no should be checked and		
Check the input output against Wiring Diagram visually during installation	All the input output shall meet the Requirements		

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 References 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:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC.
- Calibration certificates.
- Operation and Maintenance Manual.

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:

AC	:	Alternating Current
Amp	:	Amperes
cGMP	:	Current Good Manufacturing Practices
KVA	:	Kilo Volt Ampere
MCB	:	Miniature circuit breaker
MOC	:	Material of Construction
PLC	:	Programmable Logic Controller
PO	:	Purchase Order
RH	:	Relative Humidity
V	:	Volt
SOP	:	Standard Operating Procedure
URS	:	User Requirement Specification
P & ID	:	Piping & Instrumentation Diagram
NMT	:	Not More Than
NLT	:	Not Less Than
SS	:	Stain less Steel
VFS	:	Vial Filling & Stoppering 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)			