INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIAL SEALING MACHINE

EQUIPMENT ID. No.	
LOCATION	**Vial Capping Room**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

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

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PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIAL SEALING 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 Sealing Machine for ……
- 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 Sealing Machine (Make: Aegis Pharma Tech)** to be installed in the **Vial Capping Room, 'I' Block** at …….
- 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 Sealing 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.
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 Vial Sealing Machine 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 Sealing Machine
Equipment	……
Manufacturer's Name	Aegis Pharma Tech
Supplier's Name	Aegis Pharma Tech
Location of Installation	Vial Capping Room

6.0 SYSTEM DESCRIPTION:

The equipment is an automated means of cap sealing for different size of vial. The equipment has four head for the capping action. The filled vials from the vial filling machine are conveyed through the conveyor and enter into the feed worm; same will pick-up the vial and place into the star wheel where the vials pick up the caps from the cap-releasing shoe.

The filled and Stoppard vials having capped placed on their heads then pass towards the Sealing heads. Star wheel will place the vial on lifter bowl and same will hold the vial from bottom and from top. Chucks will grip the vial positively and firmly.

Single sealing roller will seal the vial during the planetary motion of vial and exit star wheel will gain pick-off the sealed vial and place on the conveyor for further operation.

The equipment can be operated either in auto mode or in manual mode. The aluminium seal vibratory bowl fitted with electromagnetic coil with pot, increases or decreases the vibration of feeder bowl. It also sense the presence of cap in the cap releasing shoe & interlocked with ON/OFF main motor and detect the tilted bottle and interlocked with the main motor.

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.

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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 Sealing Machine.		
2.	Check the proper electrical installation of Vial Sealing 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: ……

8.2 General Checks and Location Suitability:

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 Capping Room		
Room Condition	General working condition. As per GMP and production requirement		
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: ……

8.3 Installation Checks:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Dimension	1650 (L) x 1804 (H) x 1078 (W) (in mm)		
No. of Sealing Head	Nos. : 04		
Capacity	60 - 90 Vials/minute		
Direction of Machine	Left to Right		
Main Motor	Make : REMI (VEM) Type : 03 Phase Induction Motor kW : 0.75 Volt : 415 RPM : 1390 AMP : 1.86 Frequency: 50 Hz Sr. No. : 14 K-592		
Gear Box	Make : Yash Worm Gear Unit Model : YGVU Size : 250 Ratio : 10:1 Sr. No. : 12089		
Indicators	Nos. : 02 (01 Green for Power ON & Red for Clutch) Type : Led Indicators Volt : 240 V, AC Supply		
On/Off Main Switch	Make : L & T (SALZER) Quantity : 01 No.		

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

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Start/ Stop Switch	Start : Green Stop : Red Inch : Yellow Type : Push Type Button		
Limit Switch	Nos. : 04 Make : ESSER (CE)		
MCB	Make : L & T Type : C 16 Volt : 240/415 V		
Change Parts	Star Wheel, Centre Guide, Feed Worm, Die, Delivery Chute & Bowl		
Star Wheel	Nos. : 02 (In feed & Exit Out feed)		
Capping Section	Nos. : 01		
Vibratory Cap Hopper	Nos. : 01		
Dimensions of Vibratory Cap Hopper	440 (H) x 330 (W) (in mm)		
VFD A.C. Drive	Nos. : 01 Speed : 0 - 100		
VFD Vibration Controller	Nos. : 01 Speed : 0 - 100		

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:

Parts Name	Material of construction	Observation	Observed By (Engineering) Sign/Date
Die	SS 316 L		
Roller	SS 304		
Conveyor	SS 304		
Star Wheel	Bakelite		
Vibratory Bowl	SS 316 L		
Vibratory Bowl Chute	SS 316 L		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.5 Safety:

Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Well embedded equipment	For Vial Sealing 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 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
AMPS	:	Amperes
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
IQ	:	Installation Qualification
MCB	:	Miniature Circuit Breaker
MOC	:	Material of Construction
PO	:	Purchase Order
RH	:	Relative humidity
SOP	:	Standard Operating Procedure
URS	:	User Requirement Specification
P & ID	:	Piping & Instrumentation Diagram
SS	:	Stain less Steel

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)			