OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR VIAL SEALING MACHINE

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

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

CONTENTS

PHARMA DEVILS	OPERATIONAL 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 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 Sealing 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 Sealing Machine (Make: Aegis Pharma Tech)** installed in the Vial Capping Room.
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of Vial Sealing Machine.
- Successful completion of this Protocol cum Report will verify that Vial Sealing 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.
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.

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 EQUIPEMENT 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:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- Draft SOP for Operation & Cleaning of Vial Sealing Machine.
- Draft SOP for Preventive Maintenance of Vial Sealing 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 Sealing Machine.				
4.	Draft SOP for Preventive Maintenance of Vial Sealing 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 Sealing 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
Machine On /Off Switch			
Press On Switch	Machine Should be Start.		
Press Off Switch	Machine Should be Stop.		
Vibrator On /Off Switch			
Press On Switch	Vibrator Should be Start.		
Press Off Switch	Vibrator Should be Stop.		
Vibration Controller Switch			
Rotate the knob in clock wise direction.	Vibrator speed should be increased.		
Rotate the knob in anti clock wise direction.	Vibrator speed should be decreased.		
Inching Switch			
Press inching switch	Machine Should be Start.		
Release inching switch	Machine Should be Stop.		
A.C. Drive Speed Controller Knob			
Rotate the knob in clock wise direction.	Conveyor belt speed should be increased.		
Rotate the knob in anti clock wise direction.	Conveyor belt speed should be decreased.		

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	Equipment should Stop		
• Press Start Push Button	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
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
mm	:	Millimetre
Amp.	:	Ampere
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
MOC	:	Material of Construction
NLT	:	Not Less Than
HP	:	Horse Power
KW	:	Kilo Watt
SS	:	Stainless Steel
ID.	:	Identification
Kg	:	Kilo Gram
Ltrs	:	Liters
MCB	:	Miniature Circuit Break

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)			