OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SEMI-AUTOMATIC CRIMPING MACHINE

EQUIPMENT ID. No.	
LOCATION	**OINTMENT SECTION**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SEMI-AUTOMATIC CRIMPING MACHINE	PROTOCOL No.:

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PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SEMI-AUTOMATIC CRIMPING MACHINE	PROTOCOL No.:

1.0 PROTOCOL PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
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 Semi-Automatic crimping 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 Semi- automatic Crimping Machine **(Make: ……..)** installed.
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of Semi- automatic Crimping Machine.
- Successful completion of this Protocol will verify that Semi-Automatic crimping 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 Execution of Operational Qualification study as per Protocol. • Post Review of Operational Qualification Protocol after Execution.
Engineering	• Review of Operational Qualification Protocol cum Report. • To Execution Operational Qualification Activity. • Post Review of Qualification Protocol cum Report after Execution.

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR SEMI-AUTOMATIC CRIMPING MACHINE	PROTOCOL No.:

5.0 EQUIPMENT DETAILS:

Equipment Name	Semi- Automatic Crimping Machine
Equipment ID.	
Manufacturer's Name	Line speed Aerosol
Supplier's Name	Line speed Aerosol
Location of Installation	Ointment section

6.0 EQUIPEMENT DESCRIPTION:

7.0 RE - QUALIFICATION REQUIREMENTS:

7.1 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 Semi-Automatic Crimping Machine				
4	Draft SOP for Preventive Maintenance Semi-Automatic Crimping Machine				

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date:……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

7.2 Training record of validation team:

- Training shall be imparted to personnel involved in Performance Qualification activity and shall be recorded as follows;

S.No.	NAME OF EMPLOYEE	EMPLOYEE CODE	DEPARTMENT	DESIGNATION	SIGN/DATE

Trainer name……..

Inference

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Reviewed by
QA Manager
Sign/Date…….

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Operational and Functional Checks for Glass bottle / plastic bottle :

Operate the Semi-Automatic crimping machine as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function.

OPERATION	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Connect the Air supply FRL with equipment.	Compressed air pressure should be 4.0 - 6.0 Kg /Cm^2.		
Unlock the knob & lift the supporting block with the help of hand wheel	Height should be adjusted according to bottle height.		
Lock the knob at desired position	Knob should be locked		
Operate the foot paddle with help of foot	foot paddle should be work smoothly		
Keep the empty bottle on V-Block and operate the crimping machine as per procedure	Bottle should be crimped smoothly		
Press peddle Button	Crimping Activity should be Started		
Release peddle Button	Crimping Activity should be Stop		

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:

- Validation Master Plan.
- Schedule - M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- Standard operating procedure for cleaning & operation of semi- automatic crimping machine.

10.0 DOCUMENTS TO BE ATTACHED:

- 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
ID	:	Inner Diameter

17.0 POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			