INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SEMI-AUTOMATIC CRIMPING MACHINE

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

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

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

1.0 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 provide documented evidence for the Installation Qualification of Semi-Automatic crimping 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 Semi – Automatic Crimping Machine (**Make**: **Speed line Aerosol**) to be installed in the Semi – Automatic crimping machine.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Semi-automatic crimping 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.

PHARMA DEVILS	INSTALLATION 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	
Supplier's Name	
Location of Installation	

6.0 EQUIPMENT DESCRIPTION:

A Hollow SS cylindrical assembly consisting a piston inside, Assembled with crimping tool, which is operated by Compressed air pressure depend on bottle size. Height of crimping assembly shall be adjusted by knob & hand wheel mounted on top of the cylinder. Air pressure shall be controlled by pressure gauze which is assembled on lower side of the mounting S.S. table. A Press peddle available for operation of crimping machine.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Training record of validation team:

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

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

Training given by:…….

Inference

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Reviewed by
Manager QA
Sign/Date:…….

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Installation Qualification Checklist:

S.No.	Checklist	Acceptance criteria	Observation	Checked by Engineering (Sign / Date)
1.	cGMP requirement	The **Equipments** meets the cGMP requirements& all other Regulatory obligations.		
2.	Unauthorized / Unrecorded modifications	No unauthorized modifications (or) unrecorded modifications Should be takes place.		
3.	Critical parameters	All critical parts should be identified and calibrated.		
4.	Utilities	All supporting utilities should be properly connected.		
5.	Major components	The major components Should be securely anchored and protected from shock.		
6.	Physical Dammage	There should be no observable physical damage.		
7.	Equipment Identification	Equipment identification details should be available.		

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

8.2 Equipment /Instrument/System identification

REQUIRED INFORMATION	ACCEPTANCE CRITERIA	OBSERVATION	CHECKED BY ENGINEERING SIGN/DATE
The equipment is identified as (Name of Equipment)	Equipment Name should be Semi –automatic crimping machine		
Name of the Manufacturer	Manufacturer should be Line Speed Aerosol		
Name of the Supplier	Supplier should be Line Speed Aerosol		
Equipment ID Number			
Location	Ointment section 'Q' block		

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

8.3 Technical Specification of Equipment/Instrument/System:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Equipment name	Semi-Automatic Crimping machine		
Make	Speed Line Aerosol		
Pneumatically operated	Single cylinder crimping machine		
MOC	SS304		
Pneumatically cylinder Bore diameter 127mm X Stroke 70 mm	Bore diameter 127mm X Stroke 70 mm		
Collet	36 teeth		
MOC	Spring Steel		
Machine Adjustments	Crimp Diameter, Crimp Depth, Can Height, Can Diameter.		
Utility			
Compressed Air	6 kg/cm^2 100LPM-325LPM 5CFM		

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

8.4 Leveling and alignment.

Check the Levelling and Alignment and record in the below table

S.No.	METHOD	ACCEPTANCE CRITERIA	OBSERVATION	CHECKED BY ENGINEERING (SIGN/DATE)
1.	**Spirit Level Indicator:** Place the spirit level indicator at different points on the machine frame.	The air bubble of the spirit level indicator should be observed in the center.		

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
Installation	Equipment should be properly installed along with all its components		
Adequate space	The adequate space for machine operation and man movements in that area.		
Earthing	The earthling of the equipment should be done properly.		
electrical connections	The electrical connections should be done and no electrical cables or sockets are exposed to air.		
Utilities	All supporting utilities should be properly connected and safe for use.		
Ventilated area	Area should be well ventilated and safe for use.		
Civil work	All civil works (if done) should be completed and area should be safe for use and safe for man & material movements		
Guards	All moving parts of machine should be well closed and properly guarded.		

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.

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:

URS	:	User requirement specification
cGMP	:	Current Good Manufacturing Practice
PO	:	Purchase Order
SS	:	Stainless steel
SS	:	Stainless Steel
MOC	:	Material of Construction
SS	:	Stainless Steel
QA	:	Quality Assurance

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)			