PERFORMANCE QUALIFICATION PROTOCOL FOR SEMI AUTOMATIC CRIMPING MACHINE

EQUIPMENT ID. No.	
LOCATION	
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR SEMI-AUTOMATIC CRIMPING MACHINE	PROTOCOL No.:

PROTOCOL CONTENTS

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR SEMI-AUTOMATIC CRIMPING MACHINE	PROTOCOL No.:

1.0 PROTOCOL 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 that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all test parameters meet the pre-defined acceptance criteria.

3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for the Semi – Automatic crimping machine installed in Ointment section.
- This Protocol will define the methods and documentation used to qualify the Semi – Automatic crimping for PQ.

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.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation and Approval of the Performance Qualification Protocol. • Protocol Training. • Co-ordination with Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review Performance Qualification Protocol. • To co-ordinate and support Performance Qualification Activity.
Engineering	• Reviewing of qualification protocol for correctness, completeness and technical excellence. • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule.

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5.0 EQUIPMENT DETAILS:

Equipment Name	Semi-Automatic crimping machine
Equipment	
Manufacturer's Name	
Supplier name	
Location of Installation	Ointment

6.0 SYSTEM DESCRIPTION:

A Hollow S.S. cylindrical assembly consisting a piston inside, Assembled with crimping tool, which is operated by approximately 4.0- 6.0 kg/cm2 air pressure. 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 also available for operation of crimping machine.

7.0 REASON FOR QUALIFICATION:

- New equipment installed.
- After completion of the Operation Qualification of the Equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired

8.0 SITE OF STUDY:

- Ointment Section.

9.0 FREQUENCY OF QUALIFICATION:

- Once in every Two Year ±1 month.
- After any major breakdown or after major modification.
- After Change of Location.

10.0 PRE – QUALIFICATION REQUIREMENTS:

The below mentioned activities should be completed prior to commencing the performance qualification activity:

10.1 Verification of Documents:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

- SOP for Operation & Cleaning of Semi-Automatic crimping machine.
- SOP for Preventive Maintenance of Semi-Automatic crimping machine.

10.2 Training Record of Validation Team:

- All the persons involved in the execution of Qualification Protocol must be trained in all aspects of the qualification activity including the test methodology, acceptance criteria and safety precautions to be followed during working at service floor.

11.0 TESTS AND CHECKS:

11.1 Semi – Automatic Crimping Machine Crimping Method:-

1. Take 30 bottles for performance and each run shall be carried out with 10 bottles.
2. Operate the machine as per respective SOP & three run shall be carried out.
3. Bottle put on to V- block base plate.
4. Distance between Collet & kept V- block base plate bottle should be 3 mm.
5. Seal the bottle with the help of peddle button.
6. Ensure the compressed air pressure should be between 4.0 to 6.0 kg/cm^2.
7. Test observation should be recorded in Performance Qualification report.

11.1.1 Acceptance Criteria

TEST	ACCEPTANCE CRITERIA
Physical defect of crimp	No physical defect should be observed
Smoothness of crimp	Crimp should be smooth finished without sharp edge.
Leak test	No leakage bottle should be observed.

12.0 CHECKLIST OF ALL TESTS & CHECKS:

This checklist is provided to ensure that all tests or checks required for this protocol have been executed.

Tests or Checks	Executed (Yes/No)	Remarks
DQ Protocol approved		
IQ Protocol approved		
OQ Protocol approved		
SOP for Operation & Cleaning of Semi-Automatic Crimping machine		
SOP for Preventive Maintenance Semi-Automatic Crimping machine		
Verification of Documents		
Physical test		
Smoothness of Crimp		
Leak test		

13.0 REFERENCES:

- 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.
- Standard operating procedure for cleaning & operation of semi- automatic crimping machine.

14.0 DOCUMENTS TO BE ATTACHED:

- Protocol training record.

15.0 NON COMPLIANCE:

All the Non-compliances of procedure, specifications, and sampling, analysis and documentation activities shall be monitored & recorded.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an impact on operation as well as on performance of the machine & prepare final conclusion.

17.0 CHANGE CONTROL, IF ANY:

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

18.0 ABBREVIATIONS:

Asst.	:	Assistant
cGMP	:	Current Good Manufacturing Practices
QA	:	Quality Assurance
PQ	:	Performance Qualification
SS	:	Stainless steel
Nos.	:	Numbers.
SOP	:	Standard Operating Procedure
SS	:	Stain less Steel
WHO	:	World Health Organization