PERFORMANCE QUALIFICATION REPORT FOR SEMI AUTOMATIC CRIMPING MACHINE

EQUIPMENT ID. No.	
LOCATION	**Ointment**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**Nil**

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

REPORT CONTENTS

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

1.0 REPORT 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 that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all the test parameters meet the pre-defined acceptance criteria.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

3.0 SCOPE:

- The scope of this report is limited for qualification of Semi- automatic Crimping machine installed in Ointment section.
- This report provides all the relevant information of the performance qualification activity, In-process observations and analytical data of testing of collected samples.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the execution of Performance Qualification Report.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Pre-Approval and Compilation of the Performance Qualification Report. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification. • Post Approval of Performance Qualification Report after Execution.
Production	• Review of Performance Qualification Report. • To co-ordinate and support Performance Qualification Activity. • Post Approval Review of Performance Qualification Report after Execution.
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. • Post Approval Review of Performance Qualification Report after Execution.

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

5.0 EQUIPMENT DETAILS:

Equipment Name	Semi –Automatic Crimping Machine
Equipment	
Manufacturer's Name	SPEED LINE AEROSOL
Supplier's Name	SPEED LINE AEROSOL
Location of Installation	Ointment Section

6.0 PRE – QUALIFICATION REQUIREMENTS:

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.

6.1 Verification of Documents:

Record the observations for documents in the below mentioned table.

S. No.	Document Name	Document/SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (QA) Sign/Date
1.	**DQ Protocol approved**				
2.	**IQ Protocol approved**				
3.	**OQ Protocol approved**				
4.	**PQ Protocol approved**				
5.	**SOP for Operation & Cleaning of Semi-Automatic Crimping machine**				
6.	**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: ……

6.2 TEST EQUIPMENT CALIBRATION:

Instruments Name	Instrument ID	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: ……

6.3 SEMI AUTOMATIC MACHINE SETTING PARAMETERS:

S.No.	PARAMETERS	ACCEPTANCE CRITERIA	OBSERVATION		
			RUN 1	RUN 2	RUN 2
1.	Distance between Collet & kept V-block base plate bottle. should be 3 mm.	Distance Between Both collet & bottle should be 3 mm.			
2.	Compressed air Pressure	Compressed air pressure should be 4.0 – 6.0 kg/cm^2.			

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

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

7.0 TESTS AND CHECKS:

7.1 RUN NO.: 01

7.1.1 PHYSICAL TEST :

Date of test		**Product Name**	
Batch No.		**Pack Size**	

Bottle No.	Physical defect of crimp	observation
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

Acceptance Criteria: No any physical defect of crimp should be observed**.**

Checked by:
Production
Sign/Date……

Verified by:
Quality Assurance
Sign/Date……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

7.1.2 SMOOTHNESS OF CRIMP:-

BOTTLE No.	SMOOTHNESS OF CRIMP	OBSERVATION
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
Acceptance Criteria: Crimp should be smooth finished without sharp edge.		

Checked by:
Production
Sign/Date……

Verified by:
Quality Assurance
Sign/Date……..…

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

7.1.3 LEAK TEST

BOTTLE NO.	LEAK TEST	OBSERVATION
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
Acceptance Criteria: No leakage bottles should be observed.		

Checked by:
Production
Sign/Date……

Verified by:
Quality Assurance
Sign/Date……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

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

7.2 RUN NO.: 02

7.2.1 PHYSICAL TEST :

Date of test		**Product Name**	
Batch No.		**Pack Size**	

Bottle No.	**Physical defect of crimp**	**observation**
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

Acceptance Criteria: No any physical defect of crimp should be observed**.**

Checked by:
Production
Sign/date……

Verified by:
Quality Assurance
Sign/date……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

7.2.2 SMOOTHNESS OF CRIMP:-

BOTTLE NO.	SMOOTHNESS OF CRIMP	OBSERVATION
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
Acceptance Criteria: Crimp should be smooth finished without sharp edge.		

Checked by:
Production
Sign/date……

Verified by:
Quality Assurance
Sign/date……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

7.2.3 LEAK TEST

BOTTLE NO.	LEAK TEST	OBSERVATION
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
Acceptance Criteria: No leakage bottles should be observed .		

Checked by:
Production
Sign/date……

Verified by:
Quality Assurance
Sign/date……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

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

7.3 RUN NO.: 03

7.3.1 PHYSICAL TEST :

Date of test		**Product Name**	
Batch No.		**Pack Size**	

Bottle No.	**Physical defect of crimp**	**observation**
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

Acceptance criteria : No any physical defect of crimp should be observed**.**

Checked by:
Production
Sign/date……

Verified by:
Quality Assurance
Sign/date……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

7.3.2 SMOOTHNESS OF CRIMP:-

BOTTLE NO.	SMOOTHNESS OF CRIMP	OBSERVATION
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
Acceptance Criteria: Crimp should be smooth finished without sharp edge.		

Checked by:
Production
Sign/date……

Verified by:
Quality Assurance
Sign/date……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

7.3.3 LEAK TEST

BOTTLE NO.	LEAK TEST	OBSERVATION
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
Acceptance Criteria: No leakage bottles should be observed .		

Checked by:
Production
Sign/date……

Verified by:
Quality Assurance
Sign/date……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

8.0 CHECKLIST OF ALL TESTS & CHECKS:

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

S.NO.	TEST	ACCEPTANCE CRITERIA	EXECUTED (YES/ NO)
1.	Physical defect of crimp	No physical defect should be observed	
2.	Smoothness of crimp	Crimp should be smooth finished without sharp edge.	
3.	Leak test	No leakage bottle should be observed.	

Checked By
Production
Sign/Date: **……**

Verified By
Quality Assurance
Sign/Date……

Inference:

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……
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……
……

Reviewed By
Manager QA
Sign/Date: ……

9.0 DOCUMENTS TO BE ATTACHED:

- Executed Raw Data.
- Any Other Relevant Documents.

10.0 NON COMPLIANCE:

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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:

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

17.0 REPORT 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)			