PERFORMANCE QUALIFICATION REPORT FOR SINGLE HEAD SEMI AUTOMATIC TUBE FILLING, CRIMPING AND SEALING MACHINE

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

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SINGLE HEAD SEMI AUTOMATIC TUBE FILLING, CRIMPING AND SEALING MACHINE	PROTOCOL No.:

REPORT CONTENTS

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SINGLE HEAD SEMI AUTOMATIC TUBE FILLING, CRIMPING AND SEALING MACHINE	PROTOCOL No.:

1.0 REPORT PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			
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 single head semi automatic tube filling, crimping and sealing machine installed in filling room.
- 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 of Performance Qualification Report after Execution.
Quality Control	• Analytical Support (Microbiological Testing/Analysis).
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 of Performance Qualification Report after Execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	Semi automatic tube filling, crimping and sealing machine
Equipment	
Manufacturer's Name	Propack Technologies pvt. Ltd.
Model	cGMP
Supplier's Name	Propack Technologies pvt. Ltd.
Location of Installation	Filling Room

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	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 Single Head semi Automatic filling , closing and sealing machine			
6.	SOP for Preventive Maintenance Single Head semi Automatic filling , closing and sealing machine			

7.0 TESTS AND CHECKS:

7.1 Performance Evaluation For Machine Speed Optimization:

Trial No.:

Date of Test		**Equipment ID**	
Total Tube taken for test		**Pack Size**	
Parameter	**Low Speed ( )**	**Optimum Speed( )**	**High Speed ( )**
Sample after …….(min)			
Machine jam			
Tube Breakage			
Rejection			
Sample after …….(min)			
Machine jam			
Tube Breakage			
Rejection			
Sample after …….(min)			
Machine jam			
Tube Breakage			
Rejection			
Total rejection			

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date:……

Inference:

……

……

Reviewed By
Manager QA
Sign/Date: ……

7.2 Fill Weight variation test:

7.2.1 At Full Hopper :

Date of test	
Product Name	
Standard. Fill Weight - ……..gm. **(Limit: ± 1.5 % of target Filled Weight)**	
Total Operation Time	

Trial No.:

Tube No.	Minimum speed ( )			Optimum speed ( )			Maximum Speed ( )		
	Gross wt	Empty wt	Net wt	Gross wt	Empty wt	Net wt	Gross wt	Empty wt	Net wt
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									
16									
17									
18									
19									
20									

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SINGLE HEAD SEMI AUTOMATIC TUBE FILLING, CRIMPING AND SEALING MACHINE	PROTOCOL No.:

Tube No.	Minimum speed ( )			Optimum speed ( )			Maximum Speed ( )		
	Gross wt	Empty wt	Net wt	Gross wt	Empty wt	Net wt	Gross wt	Empty wt	Net wt
Min wt									
Max wt									
Average									
Wt Variation	(+)			(+)			(+)		
	(-)			(-)			(-)		

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date……

Inference:

……

……

……

Reviewed By
Manager QA
Sign/Date: ……

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SINGLE HEAD SEMI AUTOMATIC TUBE FILLING, CRIMPING AND SEALING MACHINE	PROTOCOL No.:

7.2.2 At Half Hopper:

Date of test	
Product Name	
Standard. Fill Weight - ……..gm. **(Limit: ± 1.5 % of target Filled Weight)**	
Total Operation Time	

Trial No.:

Tube No.	Minimum speed ( )			Optimum speed ( )			Maximum Speed ( )		
	Gross wt	Empty wt	Net wt	Gross wt	Empty wt	Net wt	Gross wt	Empty wt	Net wt
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									
16									
17									
18									
19									
20									
Min wt									

 PHARMA DEVILS	**PERFORMANCE QUALIFICATION REPORT FOR SINGLE HEAD SEMI AUTOMATIC TUBE FILLING, CRIMPING AND SEALING MACHINE**	**PROTOCOL No.:**

Max wt			
Average			
Wt Variation	**(+)**	**(+)**	**(+)**
	(-)	**(-)**	**(-)**

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date……

Inference:

……

……

……

Reviewed By
Manager QA
Sign/Date: ……

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SINGLE HEAD SEMI AUTOMATIC TUBE FILLING, CRIMPING AND SEALING MACHINE	PROTOCOL No.:

7.2.3 At 1/3 rd Hopper :

Date of test	
Product Name	
Standard. Fill Weight - ……..gm. **(Limit: ± 1.5 % of target Filled Weight)**	
Total Operation Time	

Trial No.:

Tube No.	Minimum speed ( )			Optimum speed ( )			Maximum Speed ( )		
	Gross wt	Empty wt	Net wt	Gross wt	Empty wt	Net wt	Gross wt	Empty wt	Net wt
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									
16									
17									
18									
19									
20									
Min wt									

Max wt			
Average			
Wt Variation	**(+)**	**(+)**	**(+)**
	(-)	**(-)**	**(-)**

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date……

Inference:

……

……

……

Reviewed By
Manager QA
Sign/Date: ……

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR SINGLE HEAD SEMI AUTOMATIC TUBE FILLING, CRIMPING AND SEALING MACHINE	PROTOCOL No.:

7.3 Leakage Test:

Date of test		**Product Name**	
Batch No.		**Fill Weight**	
Temperature		**Type of Tube**	**Lami / Aluminum**

Trial No.:……

Tube No.	Low Speed ( )	Optimum Speed ( )	High Speed ( )
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
RESULTS: The test results Complies / Not Complies as per Specification.			

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date……

Inference:

……

……

Reviewed By
Manager QA
Sign/Date: ……

7.4 Physical Test:

Date of test		**Product Name**	
Batch No.		**Fill Weight**	

Trial No.:……

Tube No.	Printing matter	Engraving	Dent	Wrinkle
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

RESULTS: The test results Complies / Not Complies as per Specification.

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date……

Inference:

……

……

……

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.

Tests or Checks	Executed (Yes/No)	Remarks
Machine Speed Synchronization		
Fill Weight Variation		
Leakage Test		
Physical Test		

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

Verified By
Quality Assurance
Sign/Date……

Inference:

……

……

……

……

……

Reviewed By
Manager QA
Sign/Date: ……

9.0 DOCUMENTS TO BE ATTACHED:

- Executed Raw Data.
- Any Other Relevant Documents.

10.0 NON COMPLIANCE:

……

……

……

……

……

11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

……

……

……

……

……

12.0 CHANGE CONTROL, IF ANY:

……

……

……

……

……

13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

……

……

……

……

……

14.0 CONCLUSION:

……

……

……

……

……

……

15.0 RECOMMENDATION:

……

……

……

……

……

……

16.0 ABBREVIATIONS:

Asst.	:	Assistant
cGMP	:	Current Good Manufacturing Practices
CQA	:	Corporate Quality Assurance
PQ	:	Performance Qualification
Vol.	:	Volume
i.e.	:	That is
SS	:	Stainless steel
Ltr.	:	Litre
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
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			