



**PERFORMANCE QUALIFICATION REPORT
FOR
DOUBLE HEAD FULLY AUTOMATIC FILLING,
CLOSING AND SEALING MACHINE**

PROTOCOL No.:

**PERFORMANCE QUALIFICATION
REPORT
FOR
DOUBLE HEAD FULLY AUTOMATIC
FILLING, CLOSING AND SEALING
MACHINE**

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



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PROTOCOL No.:

REPORT CONTENTS

S.No.	TITLE	PAGE No.
1.0	Report Pre-Approval	3
2.0	Objective	4
3.0	Scope	4
4.0	Responsibility	5
5.0	Equipment Details	6
6.0	Pre-Qualification Requirement	6
7.0	Tests & Checks	8-15
8.0	Checklist Of All Tests And Checks	16
9.0	Documents To Be Attached	17
10.0	Non Compliance	17
11.0	Deviation From Pre-Defined Specification, If Any	17
12.0	Change Control, If Any	17
13.0	Review Inclusive of Follow Up Action, If Any	17
14.0	Conclusion	18
15.0	Recommendations	18
16.0	Abbreviations	18
17.0	Report Post-Approval	19



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**PERFORMANCE QUALIFICATION REPORT
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CLOSING 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)			



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PROTOCOL No.:

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 Double head fully Automatic Filling, closing 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.



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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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Review of Performance Qualification Report.• To co-ordinate and support Performance Qualification Activity.• Post Approval of Performance Qualification Report after Execution.
Quality Control	<ul style="list-style-type: none">• Analytical Support (Microbiological Testing/Analysis).
Engineering	<ul style="list-style-type: none">• 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.



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PROTOCOL No.:

5.0 EQUIPMENT DETAILS:

Equipment Name	Double Head Fully Automatic Filling, Closing and Sealing machine
Equipment	
Manufacturer's Name	
Model	
Serial No.	
Supplier's Name	Parle Kovai 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	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 Double Head Fully Automatic filling , closing and sealing machine				
6.	SOP for Preventive Maintenance Double Head Fully Automatic				



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DOUBLE HEAD FULLY AUTOMATIC FILLING ,
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PROTOCOL No.:

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (QA) Sign/Date
	filling , closing and sealing machine				

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

.....
.....
.....

Reviewed By
Manager QA
Sign/Date:



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PROTOCOL No.:

7.2 Leakage Test :

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

Trial No.:.....

Tube No.	Low Speed (40 tubes/ min)		Optimum Speed (70 tube / min)		High Speed (100 T/M)	
	Nozzle-01	Nozzle-02	Nozzle-01	Nozzle-02	Nozzle-01	Nozzle-02
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:



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PROTOCOL No.:

7.3 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:



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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
Verification of Documents		
Fill Weight Variation		
Leakage Test		
Physical Test		

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:.....

Inference:
.....
.....
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.....
.....

Reviewed By
Manager QA
Sign/Date:



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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:

- Asst. : Assistant
- cGMP : Current Good Manufacturing Practices
- PQ : Performance Qualification
- Vol. : Volume
- i.e. : That is
- SS : Stainless steel
- Ltr. : Litre
- Nos. : Numbers.
- SOP : Standard Operating Procedure
- SS : Stain less Steel
- OFS : Double Head fully automatic Filling, closing and Sealing machine
- WHO : World Health Organization



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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)			