PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

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

REPORT CONTENTS

PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

1.0 REPORT PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Form Fill Seal Machine and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this Performance Qualification Report is limited to qualification of **Form Fill Seal Machine** (Model No. **SPEED 500 L**) installed in the **FFS Filling Room**.

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, Authorization, 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.
Engineering	• Reviewing of qualification report 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.

PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

5.0 EQUIPMENT DETAILS:

Equipment Name	Form Fill Seal Machine
Equipment ID.	……
Manufacturer's Name	Form Fill Automation (Micro Tool)
Supplier's Name	Form Fill Automation (Micro Tool)
Location of Installation	Filling Room

6.0 PRE - QUALIFICATION REQUIREMENTS:

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

- Design Qualification.
- Installation Qualification.
- Operational Qualification.
- Approved Performance Qualification Protocol
- SOP For Operation & Cleaning of Form Fill & Seal Machine
- SOP For Preventive Maintenance of Form Fill & Seal Machine

PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

7.0 TESTS AND CHECKS:

The following performance test have been carried out in order to demonstrate the Performance By Using drug Product.

7.1 Verification of Documents:

Record the observations for documents in the below mentioned table.

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)
1.	Executed and approved Design Qualification document		
2.	Executed and approved Installation Qualification document		
3.	Executed and approved Operational Qualification document		
4.	PQ Protocol approved		
5.	SOP For Operation & Cleaning of Form Fill & Seal Machine		
6.	SOP For Preventive Maintenance of Form Fill & Seal Machine		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

7.2 TEST PRODUCT BATCH INFORMATION:

S.No.	Product Name	Batch No.	Batch Size	Mfg. Date	Expiry Date

Compiled By
(QA)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

7.3 REPORT OF PERFORMANCE EVALUATION SPEED USING PRODUCT:

7.3.1 First Product Name: -

Pack Size:
Batch No.:
Date:

Test Parameters		Start of the batch (30 Second/Cycle)	Middle of the batch (30 Second/Cycle)	End of the batch 30 Second/Cycle)
A	Total No of Respoules			
	Time (by Stop Watch)			
	Time in PLC			
B	Total No of Respoules			
	Time (by Stop Watch)			
	Time in PLC			
C	Total No of Respoules			
	Time (by Stop Watch)			
	Time in PLC			

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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……

Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

7.3.2 Second Product Name:

Pack Size:
Batch No.:
Date:

Test Parameters		Start of the batch (30 Second/Cycle)	Middle of the batch (30 Second/Cycle)	End of the batch 30 Second/Cycle)
A	Total No of Respoules			
	Time (by Stop Watch)			
	Time in PLC			
B	Total No of Respoules			
	Time (by Stop Watch)			
	Time in PLC			
C	Total No of Respoules			
	Time (by Stop Watch)			
	Time in PLC			

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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……

Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

7.3.3 Third Product Name: -

Pack Size:
Batch No.:
Date:

Test Parameters		Start of the batch (30 Second/Cycle)	Middle of the batch (30 Second/Cycle)	End of the batch 30 Second/Cycle)
A	Total No of Respoules			
	Time (by Stop Watch)			
	Time in PLC			
B	Total No of Respoules			
	Time (by Stop Watch)			
	Time in PLC			
C	Total No of Respoules			
	Time (by Stop Watch)			
	Time in PLC			

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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……

Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

7.4 LEAKAGE & SEALING VERIFICATION BY USING PRODUCT:

7.4.1 First Product Name: -

Pack Size:
Batch No.:
Date:

S.No.	Start of The Batch		Middle of The Batch		End of the Batch	
	Leakage	Sealing	Leakage	Sealing	Leakage	Sealing
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						
16.						

Acceptance Criteria:

- **leak Test Should be Pass at -500 to -550 mm of Hg for 30 minute**
- **Sealing Ampoules should be round and smooth and qualified rate should be not less than 98%.**

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:……
……

Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

7.4.2 Second Product Name:

Pack Size:
Batch No.:
Date:

S.No.	Start of The Batch		Middle of The Batch		End of the Batch	
	Leakage	Sealing	Leakage	Sealing	Leakage	Sealing
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						
16.						

Acceptance Criteria:

- **leak Test Should be Pass at -500 to -550 mm of Hg for 30 minute**
- **Sealing Ampoules should be round and smooth and qualified rate should be not less than 98%.**

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

……

……

Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

7.4.3 Third Product Name:

Pack Size:
Batch No.:
Date:

S.No.	Start of The Batch		Middle of The Batch		End of the Batch	
	Leakage	Sealing	Leakage	Sealing	Leakage	Sealing
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						
16.						

Acceptance Criteria :

- **leak Test Should be Pass at -500 to -550 mm of Hg for 30 minute**
- **Sealing Ampoules should be round and smooth and qualified rate should be not less than 98%.s**

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

7.5 THICKNESS & VOLUME VERIFICATION BY USING PRODUCT:

7.5.1 First Product Name: -
Pack Size:
Batch No.:
Date:

S.No.	Start of The Batch		Middle of The Batch		End of the Batch	
	Volume	Thickness	Volume	Thickness	Volume	Thickness
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						
16.						

Acceptance Criteria :

- **NLT 5.2 ± 0.1 ml of Filled Volume,**
- **Wall Thickness of Filled Respoules NLT 0.6 mm – 0.8 mm**

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:……
……

Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

7.5.2 Second Product Name:

Pack Size:
Batch No.:
Date:

S.No.	Start of The Batch		Middle of The Batch		End of the Batch	
	Volume	Thickness	Volume	Thickness	Volume	Thickness
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						
16.						

Acceptance Criteria :

- **NLT 5.2 ± 0.1 ml of Filled Volume,**
- **Wall Thickness of Filled Respoules NLT 0.6 mm – 0.8 mm**

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

……

……

Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

7.5.3 Third Product Name:
Pack Size:
Batch No.:
Date:

S.No.	Start of The Batch		Middle of The Batch		End of the Batch	
	Volume	Thickness	Volume	Thickness	Volume	Thickness
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						
16.						

Acceptance Criteria :

- **NLT 5.2 ± 0.1 ml of Filled Volume,**
- **Wall Thickness of Filled Respoules NLT 0.6 mm – 0.8 mm**

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

……

……

Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

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.	Name of Test or Check	Execution (Yes/No)	Remark	Verified By (Sign & Date)
1.	Performance Evaluation For Machine Speed Optimization			
2.	Test for volume verification			
4.	Test For Sealing Quality			
5.	Wall Thickness Test			
6.	Test For Leak Test			

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

9.0 DOCUMENTS TO BE ATTACHED:

- 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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PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

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
CQA	:	Corporate Quality Assurance
DQ	:	Design Qualification
IQ	:	Installation Qualification
mm	:	Millimetre
No.	:	Number
OQ	:	Operational Qualification
PQ	:	Performance Qualification
SOP	:	Standard Operating Procedure
SS	:	Stain less Steel
AFM	:	Ampoule Filling & Sealing Machine
WHO	:	World Health Organization
PVT	:	Private
LTD.	:	Limited
ID.	:	Identification
RPQ	:	Report performance qualification

PERFORMANCE QUALIFICATION REPORT FOR FORM FILL SEAL MACHINE

17.0 REPORT POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			