



**PERFORMANCE QUALIFICATION
REPORT
FOR
BLOW FILL & SEAL MACHINE-603**

EQUIPMENT ID No.	
LOCATION	FILLING ROOM
DATE OF QUALIFICATION	
SUPER SEDES REPORT No.	NIL



PERFORMANCE QUALIFICATION REPORT FOR BLOW FILL & SEAL MACHINE

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PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR BLOW 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)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



PERFORMANCE QUALIFICATION REPORT FOR BLOW FILL & SEAL MACHINE

2.0 OBJECTIVE:

- To compile the Validation report carried out as per Protocol for BFS-603 Filling Machine installed in LVP Line used to provide the product consistently, within the specified acceptance limits, when operated as per the standard operating procedures.

3.0 SCOPE:

- The Report covers all aspects of Performance Qualification for the BFS 603 Filling Machine installed in the Filling Roomr.

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 Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Control	<ul style="list-style-type: none">• Preparation of Reports and submission to Quality Assurance Department.• To conduct Validation activity as per the Approved Protocol.• To provide analytical support for validation activity.
Quality Assurance	<ul style="list-style-type: none">• To compile and approval of report.• To monitor all Validation Activities and ensure the Validation is carried out as per the Protocol.• To review Report for completeness and Technical Accuracy.
Production	<ul style="list-style-type: none">• Review of Performance Qualification Report.• To co-ordinate and support Performance qualification Activity.
Engineering	<ul style="list-style-type: none">• Review of Performance Qualification Report.• To co-ordinate and support Validation Activity.• Responsible for Trouble shooting during execution (If Occurs).



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5.0 EQUIPMENT DETAILS:

Equipment Name	Blow Fill & Seal Machine-603
Equipment ID No.	
Manufacturer's Name	M/s Weiler Engineering Inc.
Supplier's Name	M/s SteriMax Engineering Pvt. Ltd.
Place of Installation	Filling Room

6.0 PRE-QUALIFICATION REQUIREMENTS :

6.1 SYSTEM PRE-REQUISITES:

S.No.	DOCUMENT NAME	DOCUMENT/ SOP No.	COMPLETED (YES/NO)	VERIFIED BY (SIGN & DATE) QA

6.2 TEST EQUIPMENT CALIBRATION:

S.No.	EQUIPMENT/ INSTRUMENTS NAME	EQUIPMENT/ INSTRUMENTS I.D NO.	CALIBRATION DONE ON	CALIBRATION DUE ON	VERIFIED BY (SIGN & DATE) QA



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6.3 TRAINING OF EXECUTION TEAM:

S.No.	Name of Trainee	Department	Designation	Acceptance Criteria	Signature of Trainee	Checked By (Sign & Date) QA
1.0				All personnel involved in execution of protocol shall be trained in the required procedure and shall be documented.		
2.0						
3.0						
4.0						
5.0						
6.0						
7.0						
8.0						
9.0						
10.0						

Name of the Trainer: _____

Inference:

Reviewed By:
(Manager QA)
(Sign & Date).....



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7.0 TESTS AND CHECKS:

7.1.1 AIR VELOCITY TEST OF FILLING ZONE:

Date of Test		Equipment ID No.	
Name of Instrument		Block / Area	
Test Instrument Calibrated done on		Test Instrument Calibration due on	

Location	Velocity [FPM]	Average Velocity [FPM]

ACCEPTANCE CRITERIA:

- Average Velocity across the filter should be within the range of $90 \pm 20\%$ FPM.

Compiled by:
(QA)
(Sign & Date).....

Inference:

Reviewed By:
(Manager QA)
(Sign & Date).....



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7.1.2 HEPA FILTER INTEGRITY TEST (PAO TEST) REPORT:

Date of Test		Equipment ID No.	
Name of Instrument		Block	
Test Condition		Area	
Test Instrument Calibrated on		Test Instrument Calibration due on	

Date	Area Name	HEPA ID. /S. No.	Acceptance Criteria	Observation (% of Leakage)
			The PAO penetration/leak through HEPA filters should not be greater than 0.01% of the upstream PAO concentration.	

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(QA)
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7.1.3 NON - VIABLE PARTICLE COUNT TEST:

Date of Test		Equipment ID No.	
Name of Instrument		Block	
Test Condition		Area	
Test Instrument Calibrated on		Test Instrument Calibration due on	

Filter No.	Particle Size	Particle Count at Different Location						Remark
		First day		Second Day		Third Day		
		Location		Location		Location		
		L1	L2	L1	L2	L1	L2	
01	$\geq 0.5\mu\text{m}$							
	$\geq 5.0\mu\text{m}$							

ACCEPTANCE CRITERIA:

- Not more than 3520 for 0.5 μm particle and 20 for 5.0 μm particle in 1m³ of air at static condition.

Compiled by:

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Inference:

Reviewed By:

(Manager QA)

(Sign & Date).....



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7.1.4 VIABLE PARTICLE MONITORING (ACTIVE AIR SAMPLING):

Date of Exposure		Sample Volume	
Test Condition		Block/ Area	
1st Incubation Temperature & time	20-25° C for 72 hrs.	2nd Incubation Temperature & time	30-35° C for 48 hrs.
Media Used		Autoclave Media Reference No.	
Test No.		Date of Report	

Date	Location No.	Counts	Remarks
	L 1		

ACCEPTANCE CRITERIA: Microbial counts should be less than 1 CFU/m³.

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7.2 VERIFICATION OF SPEED OF THE MACHINE:

Product Name		Filling Speed	
Date		Block / Area	
Rejection Limit	NMT 1.0 %		

Trial-1

Machine Speed:- 3000 Bottles / hrs

Time (in hrs)		No. of Filled Bottles (A)	No. of Rejected Bottles (B)	Nature of Rejection
From	To			

Rejection % = $\frac{B \times 100}{A} = \frac{\dots\dots\dots \times 100}{\dots\dots\dots} = \dots\dots\dots \%$

Trial-2

Machine Speed:- 3000 Bottles / hrs

Time (in hrs)		No. of Filled Bottles (A)	No. of Rejected Bottles (B)	Nature of Rejection
From	To			

Rejection % = $\frac{B \times 100}{A} = \frac{\dots\dots\dots \times 100}{\dots\dots\dots} = \dots\dots\dots \%$



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Trial-3

Machine Speed:- 3000 Bottles / hrs

Time (in hrs)		No. of Filled Bottles (A)	No. of Rejected Bottles (B)	Nature of Rejection
From	To			

Rejection % = $\frac{B \times 100}{A} = \frac{\dots\dots\dots \times 100}{\dots\dots\dots} = \dots\dots\dots \%$

Compiled by:
(QA)
(Sign & Date).....

Inference:

Reviewed By:
(Manager QA)
(Sign & Date).....



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PERFORMANCE QUALIFICATION REPORT FOR BLOW FILL & SEAL MACHINE

Trial-3

Date:.....

Time:.....

Cavity No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Net Fill Weight (in gram)														
Fill Volume (in ml)														
Observed By														
Checked By														

Compiled by:
(QA)
(Sign & Date).....

Inference:

Reviewed By:
(Manager QA)
(Sign & Date).....



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PERFORMANCE QUALIFICATION REPORT FOR BLOW FILL & SEAL MACHINE

Trial-3

Date:.....

Time:.....

Cavity No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Weight of Empty Bottle (in gram)														
Observed By														
Checked By														

Compiled by:

(QA)

(Sign & Date).....

Inference:

Reviewed By:

(Manager QA)

(Sign & Date).....



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7.5 VERIFICATION OF LEAK TEST OF THE CONTAINERS:

Cycle-1

Product Name		Filling Speed	
Date		Block / Area	
Applied Pressure	0.75 to 1.0 kg/cm ²	Acceptance Criteria	Leaked Bottles NMT 0.1%
Leak Test Equipment ID			

Bottle. No.	Parameter		
	Leakage Observation		
	Initial	Middle	End
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			



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Cycle-2

Bottle. No.	Parameter		
	Leakage Observation		
	Initial	Middle	End
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			

Cycle-3

Bottle. No.	Parameter		
	Leakage Observation		
	Initial	Middle	End
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			



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Bottle. No.	Parameter		
	Leakage Observation		
	Initial	Middle	End
10.			
11.			
12.			
13.			
14.			

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(Sign & Date).....

Inference:

Reviewed By:
(Manager QA)
(Sign & Date).....



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Bottle No.	Parameter													
	Tip Formation	Head Formation	Caller Formation	Head Ring Formation	Extra Plastic on Neck	Neck Breaking Problem	Dip Line	Hanger Physical Strength	Embossing Problem	Rough surface problem	Smooth with no Scratches	Joining Lines & Sealing should be smooth	Foreign particle	Transparency
4.														
5.														
6.														
7.														
8.														
9.														
10.														
11.														
12.														
13.														
14.														

Compiled by:
(QA)
(Sign & Date).....

Inference:

Reviewed By:
(Manager QA)
(Sign & Date).....



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Bottle No.	Parameter : Thickness Observation											
	Initial				Middle				End			
	Left Side (in mm)	Right Side (in mm)	Front (in mm)	Back. (in mm)	Left Side (in mm)	Right Side (in mm)	Front (in mm)	Back. (in mm)	Left Side (in mm)	Right Side (in mm)	Front (in mm)	Back. (in mm)
14.												

Compiled by:
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(Sign & Date).....

Inference:

Reviewed By:
(Manager QA)
(Sign & Date).....



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7.8 STERILITY OF EMPTY CONTAINER, BLOW AIR & BLOWING AIR:

Product Name		Block / Area	
Date			

Bottle No.	Sterility	
	Empty Container	
	Result +ve =Growth -ve = No growth	Checked By
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		



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Compiled by:
(QA)
(Sign & Date).....

Inference:

Reviewed By:
(Manager QA)
(Sign & Date).....



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8.0 CHECKLIST OF ALL TESTS AND CHECKS:

TESTS OR CHECKS	EXECUTED [Y/N]	Checked By (Sign & Date) QA	COMMENT
1. Filling zone verification)			
A) Air Velocity Measurement Test			
B) Filter Integrity Test			
B)- Non viable particle count test			
C)- Viable Particle Count (By Active Air Sampling)			
2. Verification of Speed of The Machine			
3. Verification of volume			
4. Weight Verification of Empty Containers			
5. Verification of Leak Test of the Containers			
6. Verification of Physical Appearance of Bottles			
7. Verification of Wall Thickness			
8. Sterility of Empty Container			

Compiled by:
(QA)
(Sign & Date).....

Inference:

Reviewed By:
(Manager QA)
(Sign & Date).....



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9.0 DOCUMENTS ATTACHED:

- Raw data of Microbiological Analysis
- Calibration Certificates for Anemometer
- Calibration Certificates for Airborne particle counter
- Calibration Certificates for Measuring Cylinder.
- Calibration Certificates for Vernier Caliper

10.0 NON COMPLIANCE:

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.....
.....

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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.....

12.0 CHANGE CONTROL, IF ANY:

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.....
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PERFORMANCE QUALIFICATION REPORT FOR BLOW 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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PERFORMANCE QUALIFICATION REPORT FOR BLOW FILL & SEAL MACHINE

16.0 ABBREVIATIONS:

QA	:	Quality Assurance
QC	:	Quality Control
No.	:	Number
Ltd.	:	Limited
ID No.	:	Identification Number
ml	:	Milliliter
FPM	:	Feet per Minute
BFS	:	Blow Fill & Seal



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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)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			