PERFORMANCE QUALIFICATION PROTOCOL FOR FORM FILL SEAL MACHINE

EQUIPMENT ID. No.	
LOCATION	**Filling Room**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

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PROTOCOL CONTENTS

PERFORMANCE QUALIFICATION PROTOCOL FOR FORM FILL SEAL MACHINE

1.0 PROTOCOL – 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)			

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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 PQ protocol cum report is limited to qualification of **Form Fill Seal Machine** (**Model No.:** Speed 500 L) installed in the **FFS Filling Room.**

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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 overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Approval and Authorization of the Performance Qualification Protocol. • Co-ordination with Production and Engineering to carryout Performance Qualification activity.
Production	• Review of Performance Qualification Protocol. • To Co-ordinate and support for execution of Qualification study as per Performance Qualification Protocol.
Engineering	• Review of Performance Qualification Protocol. • To co-ordinate and support Operational Qualification Activity.

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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 EQUIPEMENT DESCRIPTION:

Form Fill Seal Process is the sterile and Pyrogen free molding of the bottles or ampoules directly from the extruded PE in water cooled blow moulds with an immediate Sterile filling of product, followed by a hermetic sealing of the container in one step and under aseptic conditions in the same machine. This assures a high reliability of the process as well as product.

FFS Machine continuously produces hot plastic parisons, which are enclosed by a blow moulds. When the main mould closes the bottom part is hermetically sealed.

A special mandrel unit is lowered into mould neck and shapes the container with compressed air. In a process the fill product exactly measured by FFS machine dosing unit is filled into the formed hollow containers.

The upper part of parison still unformed is sealed by the closing motion of the head mould while the special mandrel unit retracts. Simultaneously a vacuum forms the hermetic closure. The package entirely produce filled and sealed in FFS machine is released. The cycle then repeats.

Form Fill Automation FFS machine consist of following major stations:

1. **Basic Structure:** The base frame is welded with SS304 and includes four shock leveling pads. The entire upper portion of the machine is enclosed in polished stainless steel including front doors, belt guards and electrical cabinet.
2. **Mold Clamp and Carriage Assembly:** The carriage travel is 20'' and electrically actuated by a servo motor with the help of servo drive. Main Mold clamp is actuated by 3 cylinders of 4" bore cylinder. The main mold clamp stroke is 1-1/2" per side and provides a 6 ton closing force. Seal molds are actuated by a 2 x 2 stroke cylinders and provide 1- 1/2 tons of closing force. All hydraulic cylinders are electro less nickel plated and rated at 3000 p.s.i
3. **Extrusion System:** The 60 mm, 24:1 L/D thermoplastic extruder has a mixing tip on the screw and bimetallic lining in the barrel. The barrel temperature is controlled in three zones by separate

cast aluminum heaters with internal water coils for cooling. The plastic is supplied through a stainless steel hopper and water cooled feed throat. The extruder is driven by a 20 HP AC variable speed motor, through a double reduction gear box. Extruder output is 100lbs/hour maximum of polypropylene resin.

4. **Pneumatic System:** System consists of a coalescing filter, regulator and manifold mounted solenoid control valves for ballooning, blowing and other machine functions. The supply should be oil free, dry, clean air at 15 cfm @ 6 bar.
5. **Vacuum System:** Vacuum is supplied to four separately controlled zones on the machine. The system consist of a vacuum reservoir and mainfold mounted regulators and solenoid valves. The supply must be vacuum rated at 200 CFM @ 25hg
6. **Cooling System:** The flow of coolant water must be 30 liter/hr at 3.5 bar, 10 °C with one supply and one return line. The FFS Machine is internally equipped with separate cooling circuits for the main molds, seal mould, holding jaws, extruder feed throat zone, hydraulic power unit and extruder barrel cooling system. The mold coolant circuits have flow controls and temperature gauges.
7. **Parison cut off mechanism:** An air cylinder actuated hot knife is electrically actuated by a solid state controller and 110 kva transformer.
8. **Smoke Arrester:** The system consist of blower on the parison cut off knife which exhausts air to outside of the machine clean room.
9. **Filling System:** Pneumatically controlled pressure fill nozzle assembly.
10. **Product Filling Equipment:** Pressure equalizing and buffer tank with sterile steam recharging equipment, hermetically closed, dust proof, sterilizable with steam, for product to be supplied. Sterile steam recharging through electro-pneumatic valve control is automatically given for products which are consuming the steam cushion. Thus product pre-pressure is maintained between 0.4 – 0.8 Bar over pressure. Total volume of tank depending on dosing quantity of one cycle 40-60 liters, operation pressure max 2.5 bar over pressure.

    Aseptic equipment for machine equipped with time pressure dosing system, with remote controlled valve connection through program selector on switch cabinet with following automatic stages:

    A. CIP
    B. SIP
    C. Filter Drying
    D. Production

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The aseptic equipment maintains sterile conditions and consists of following main assemblies: Filtering of sterile air, Sterile air over pressure system, Steam barrier, Steam connection, Condensing trap.

7.0 REASON FOR QUALIFICATION:

New equipment in FFS Filling Area.

8.0 SITE OF STUDY:

FFS Filling Area.

9.0 FREQUENCY OF QUALIFICATION:

- Once in a year.
- After any major breakdown or after major modification.
- Periodically

10.0 PRE - QUALIFICATION REQUIREMENTS:

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

- Design Qualification.
- Installation Qualification.
- Operational Qualification.
- SOP for Operation & Cleaning of Form Fill Seal Machine.
- SOP for Preventive Maintenance of Form Fill Seal Machine.

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11.0 TESTS AND CHECKS:

11.1 PERFORMANCE EVALUATION FOR SPEED OPTMIZATION

OBJECTIVE:

To establish machine speed optimization by 5 ml Respoules.

EQUIPMENT/INSTRUMENT USED:

Stop Watch/PLC Timer

METHOD APPLIED:

- The test should be carried out on 5 ml size of Respoules.
- Load the LDPE Granule in FFS filling Machine.
- Switch "ON" the machine & Operate as per **SOP.**
- Set the machine speed (Respoules/Minute) through HMI as per below table.

Respoules Size	30 Second/cycle
5 ml	160 respoules

- Start the machine Optimum speed & count the Respoules for 10 minute
- Final machine output shall be decided & verified after performing the test.

11.2 TEST FOR VOLUME VERIFICATION:

11.2.1 OBJECTIVE: To establish that the filling volume variation in the Filled Respoules by Machine, take 16 filled Respoules from each Stage

11.2.2 EQUIPMENT/INSTRUMENT USED:

Calibrated Measuring Cylinder

11.2.3 METHOD APPLIED:

- The test should be carried out at Initial, Middle & end of the batch for 5 ml of Respoules.
- Transfer the Liquid & LDPE granule to filling Machine.
- Switch "ON" the machine & Operate as per SOP.
- Collect 16 Filled Respoules from the machine at initial, middle and End stage. Measure Filled Volume through calibrated measuring cylinder
- Perform the test for 5 ml size Ampoules.
- Perform the test by using three commercial batch.

11.2.4 ACCEPTANCE CRITERIA:

S.No.	Ampoule Size	Filled Volume Limit
1.	5 ml	5.2 ± 0.1 ml

11.2.5 RESULT RECORDING:

Record the results in Performance Qualification Report.

11.3 TEST FOR SEALING QUALITY:

11.3.1 OBJECTIVE: To qualify for the Sealing Quality by Visually. Sealing Should be free From LDPE Burr and Should be Smooth

11.3.2 EQUIPMENT/INSTRUMENT USED:

NA

11.3.3 METHOD APPLIED:

Perform the test for 5 ml size Ampoules. By Visually.

11.3.4 ACCEPTANCE CRITERIA:

Sealing Ampoules should be round and smooth and qualified rate should be not less than 98%.

11.3.5 RESULT RECORDING:

Record the results in Performance Qualification Report.

11.4 TEST FOR WALL THICKNESS :

11.4.1 OBJECTIVE: To qualify for the Wall Thickness of Filled Respoules.

11.4.2 EQUIPMENT/INSTRUMENT USED:

Calibrated Vernier Caliper

11.4.3 ACCEPTANCE CRITERIA:

Wall Thickness of Filled Respoules NLT 0.6 mm – 0.8 mm

11.4.4 RESULT RECORDING:

Record the results in Performance Qualification Report.

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11.5 LEAK TEST:

11.5.1 OBJECTIVE: To qualify for the Effective Sealing of Filled Respoules.

11.5.2 EQUIPMENT/ INSTRUMENT USED:

Vacuum Leak Tester

11.5.3 ACCEPTANCE CRITERIA: leak Test Should be Pass at -500 to -550 mm of Hg for 30 minute.

11.5.4 RESULT RECORDING:

Record the results in Performance Qualification Report.

12.0 CHECKLIST OF ALL TESTS & CHECKS: All Test & Checks for Performance Qualification of Form Fill & seal Machine are 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: ……

13.0 REFERENCES

- Vendor Documents .
- As Per VMP

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14.0 DOCUMENTS TO BE ATTACHED:

- Any other relevant documents.

15.0 NON COMPLIANCE:

- In case of any Non compliance observed during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of Non compliance. If Non compliance is acceptable and it does not have an impact on performance of the Qualification, prepare final conclusion.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an Impact on performance of the Qualification, prepare final conclusion & prepare final conclusion.

17.0 CHANGE CONTROL, IF ANY

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an Impact on performance of the Qualification, prepare final conclusion & prepare final conclusion

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18.0 ABBREVIATIONS:

No.	:	Number
WHO	:	World Health Organization
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
SOP	:	Standard Operating Procedure
MOC	:	Material of Construction
SS	:	Stain less Steel
FFS	:	Form Fill Seal machine
CFM	:	Cubic Feet Per minute
RPM	:	Revolution Per minute
CIP	:	Clean in Place
SIP	:	Steam in Place