



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR FORM FILL SEAL
MACHINE**

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
FORM FILL SEAL MACHINE**

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



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR FORM FILL SEAL
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QUALITY ASSURANCE DEPARTMENT

**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR FORM FILL SEAL
MACHINE**

1.0 PROTOCOL 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)			



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR FORM FILL SEAL
MACHINE**

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of **Form Fill Seal Machine** Model No. **SPPED 500 L** for
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of **Form Fill Seal Machine** (Model No.: **SPPED 500 L**) to be installed in the **FFS Room, 'I' Block** at
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Form Fill Seal Machine.



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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	<ul style="list-style-type: none">• Preparation, Review, Authorized and Compilation of the Installation Qualification Protocol cum Report.• Co-ordination with Production and Engineering to carryout Installation Qualification.• Monitoring of Installation Qualification Activity.• Post Approval of Installation Qualification Protocol cum Report after Execution.
Production	<ul style="list-style-type: none">• Review & Pre Approval of Protocol cum Report.• To Co-ordinate and support for Execution of Qualification study as per Protocol.• Post Approval of Installation Qualification Protocol after Execution.
Engineering	<ul style="list-style-type: none">• Review & Pre Approval of Installation Qualification Protocol cum Report.• Co-ordination, Execution and technical support in Installation Qualification Activity.• Calibration of Process Instruments.• Responsible for Trouble Shooting (if occurs during execution).• Post Approval of Installation Qualification Protocol after Execution.



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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, FFS Section

6.0 SYSTEM DESCRIPTION:

Form Fill Seal Process is the sterile and Pyrogen free moulding 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 psi.
- 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



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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 manifold 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 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- Piping and instrumentation diagram.
- Electrical circuits diagram.
- Technical specification of equipment.
- Calibration certificate of components.
- Certificate of material of construction of components.

7.1.1 Procedure:

- Verify the above mentioned documents for availability, completeness and approval status
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum Report.

7.1.2 Acceptance Criteria:

- All the documents should be available, complete and approved by respective authorities.



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8.0 CRITICAL VARIABLES TO BE MET:

8.1 GENERAL CHECKS AND LOCATION SUITABILITY:

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Grouting and Mounting	Should be properly grouted and mounted.		
Leveling	Should be properly balanced and leveled.		
Edges of parts	Metal parts should be properly ground without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	FFS Room, 'T' Block		
Room Condition	Temperature : NMT 25°C RH : NMT 55%		
Illumination	NLT 300 Lux		
Working space around the Equipment.	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

Checked By (Production)

Sign/Date:

Verified By (Quality Assurance)

Sign/Date:

Inference:

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Reviewed By (Manager QA)

Sign/Date:



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR FORM FILL SEAL MACHINE

8.2 EQUIPMENT VERIFICATION

8.2.1 TECHNICAL SPECIFICATIONS:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Make	Micro Tool		
Model	SPEED 500 L		
Type	2 stations/ 8 parison (160 cavity)		
Output	19000-20000 Pcs/hr		
Overall Dimensions	6000 mm x 8000mm x 3000 mm		
Srew			
Diameter	60 mm x 2 Nos		
Length	L/D 24:1		
Speed	0-75 RPM		
Extruder Motor			
Make	Crompton		
Type	3 Phase induction motor		
Capacity	25 HP/18.5 Kw		
Quantity	2 Nos		
Hydraulic Pump Motor			
Make	Crompton		
Type	3 Phase induction motor		
Capacity	15 HP		
RPM	1460		
Quantity	2 Nos		
Gear Box			
Make	Form Fill Automation		
Type	Helical		
Ratio	15:1		
Moulds			
Make	Form Fill Automation		
MOC	Aluminium Bronze		



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MACHINE**

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Mould Clamping Force	Head – 2 Nos , Body – 4 tone		
Pressure Gauges			
Make	Hi- Tech		
Type	Bourdon		
Range	0-2000 PSI		
Pressure Gauges			
Make	SMC		
Range	0-20 Kg		
Pneumatic System Regulators			
Make	SMC		
Flow Control Valves			
Make	SMC		
Cylinders			
Make	SMC		
Solenoid Valves			
Make	SMC		
Nos	120		
Pipe Fittings			
Make	Pheonix		
Electric Heaters			
Make	Form Fill Automation		
Type	Band Heaters with heat insulation		
Quantity			
Hydraulic System Locking Cylinder			
Make	Form Fill Automation		
Stroke	150		
Shifting Cylinder			
Make	Form Fill Automation		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Stroke	Servo		
Extruder Up Down Cylinder			
Make	Form Fill Automation		
Stroke	75		
Pin Up Down Cylinder			
Make	Form Fill Automation		
Stroke	150		
Parison Control Cylinder			
Make	Form Fill Automation		
Stroke	40		
Vacuum Gauges			
Make	Hi- Tech		
Type	Bourdon		
Range	0 to -750 mm of WC		
PLC			
Make	Ultra Industries		
VFD			
Make	Teknik		

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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8.2.2 INSTALLATION CHECKS:

S.No.	SPECIFICATION	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
1.	All the M.S base bolts provided for packing purpose to be replaced by SS base bolts with rubber pad.		
2.	Set the height of the machine by adjusting the base bolts to match the height.		
3.	Also proper leveling of the machine should be done using appropriate spirit level by adjusting the base bolts.		
4.	Carefully examine the wiring diagram of the machine before making any connection.		
5.	Connect the cables to the panel to their respective connectors.		
6.	Check wires for proper polarity of the AC motor.		
7.	Connect the sensor cables to the terminal in the panel.		
8.	Make sure that 'earthing' is provided.		
9.	After all wires connected, connect the mains cable.		
10.	Clean all the SS guides, bridge plates and star wheel with IP solution.		

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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8.3 MOC Verification List:

Parts Name	Material of construction	Observation	Observed By (Engineering) Sign/Date
Machine Frame & Locking Unit	SS304		
Manifold	SS316L		
Filling unit	SS316L		
Filling Nozzle	SS316L		
Filling Tank	SS316L		
Mould	Pre Hardened Non Corrosive SS		
Parison Holder	SS304		
Hopper	SS304		
Heater	Asbestos		

**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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8.4 Utility Verification List:

Critical variables	Acceptance criteria	Observation	Observed By (Engineering) Sign/Date
Electrical Supply	Voltage : 415 V , 3 Phase Frequency : 50 HZ Power : 60 KW		
Room Condition	Temperature : NMT 25 °C RH : NMT 55 %		
Compressed Air(Oil Free)	Presure : 8-10 Kg/cm ² Capacity : 30 CFM		
Vacuum	200 CFM at 25 HG		
Chilled Water	Temperature : 16 °C Flow Rate : 25-30 LPM @ 3.5 Bar		
Normal Water	Consumption : 150 Lit/ min		

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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8.5 Safety:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Hardware Emergency switch at Operator Console	For Operator Safety.		
Liquid low level – Machine stop	For safety of the batch & the process.		
Motor overload Relay	For Motor & equipment protection.		
No Respoule No Filling Sensor	To avoid the wastage of product.		
Earthing	Earthing to be provided to Control Panel.		
Joints	Welding of joints without any welding burrs.		
Metal Parts	All the metal parts should be Properly grounded without sharp edges.		
Leveling And Balancing	Equipment should be properly balanced & leveled		
Electrical Wiring/Components And Earthing	All electrical wirings and components should be mounted in enclosed cabinet with proper earthing.		
Guards	Guards for all Moving Parts		
Noise Level	Below 80 db		
MCB	MCB is provided so that when there is an overload in current or any short circuit then the MCB trips.		
All Drive Arrangements	With all covers and guards		
Alarms & Interlocks	System Give Alarm		

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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8.6 Control Panel Check:

Test Particulars	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Check that Machine is connected with control panel. Record the details of PLC	Machine should be connected with control panel. PLC make, model no. , serial no should be checked and verified		
Check the input output against Wiring Diagram visually during installation	All the input output shall meet the Requirements		

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 REFERENCES:

- Design Qualification Document of Party.

10.0 DOCUMENTS TO BE ATTACHED:

- Purchase order.
- Any other relevant documents

11.0 DEVIATION FROM PRE-DEFINED 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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**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR FORM FILL SEAL
MACHINE**

14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

mm	:	Millimeter
MOC	:	Material of Construction
PO	:	Purchase Order
RH	:	Relative Humidity
SS	:	Stainless Steel
KG	:	Kilogram
FFS	:	Form Fill Seal
IQ	:	Installation Qualification
IB	:	Injection block
No	:	Number
ID.	:	Identification
AC	:	Alternating Current
NLT	:	Not Less Than
NMT	:	Not More Than
CFM	:	Cubic Feet Per minute
RPM	:	Revolution Per minute
CIP	:	Clean in Place
SIP	:	Steam in Place
PLC	:	Programmable Logic Control



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MACHINE**

17.0 PROTOCOL 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)			