



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR FORM FILL SEAL MACHINE

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

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	NIL



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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)			



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2.0 OBJECTIVE:

- To prepare the Design Qualification on the basis of URS, Purchase Order and information given by Supplier.
- The purpose of Design qualification is to ensure that all Critical Aspects of Process/Product requirement, cGMP and Safety have been considered in designing the equipment and is properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of **Form Fill Seal Machine** for
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & IDs provided by Vendor shall be verified during Design Qualification.



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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, Compilation Review and Authorization of Design Qualification Protocol cum Report.• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.• Review of Qualification Protocol cum Report after Execution.• Co-ordination with Production and Engineering to carryout Design Qualification.• Monitoring of Design Qualification Activity.
Production	<ul style="list-style-type: none">• Review of the Protocol cum Report.• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.• Review of Design Qualification Protocol cum Report after Execution.
Quality Control	<ul style="list-style-type: none">• Review of Design Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review of Design Qualification Protocol cum Report.• Assist in the Preparation of the Protocol cum Report.• To co-ordinate and support the Activity.• To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e.<ul style="list-style-type: none">➤ GA Drawing.➤ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/ brochures.➤ Details of utilities.➤ Identification of components for calibration.➤ Material of construction of all components.➤ Brief Process Description.➤ Safety Features and Alarms.• Review of Design Qualification Protocol after Execution.



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5.0 PROJECT REQUIREMENT:

To confirm the safe delivery of the Equipment from the supplier Site. To ensure that no Unauthorized and/or Unrecorded design modification shall take place. If at any point in time, any change is desired in the mutually agreed design, Change Control procedure shall be followed and documented.

- The Form Fill Seal Machine &, its associated components are designed in accordance with cGMP principles.

6.0 BRIEF EQUIPMENT 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 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 aluminium 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 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared for The manufacturer of equipment ensures complies with User Requirement Specification.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS/PRODUCT PARAMETERS:

Critical variables	Acceptance criteria	Reference
Application: Ampoule Filling & Sealing Machine is used for ampoule filling and sealing for liquid injection.	Should be able to filled volume accurately with minimal spillage.	Process Requirement
Working: The machine works on linear intermittent filling principle.	Filling of material should be highly accurate.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

8.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

Critical variables	Acceptance criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	Voltage : 415 V , 3 Phase Frequency : 50 HZ Power : 60 KW	GMP Requirement
Room Condition	Temperature : NMT 25 °C RH : NMT 55 %	Process Requirement
Compressed Air(Oil Free)	Presure : 8-10 Kg/cm ² Capacity : 30 CFM	Process Requirement
Vacuum	200 CFM at 25 HG	Process Requirement
Chilled Water	Temperature : 16 °C Flow Rate : 25-30 LPM @ 3.5 Bar	Process Requirement
Normal Water	Consumption : 150 Lit/ min	Process Requirement



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8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

Critical Variables	Acceptance Criteria	Reference
Make	Form Fill Automation	Design Requirement
Model	SPEED 500 L	Design Requirement
Type	2 stations/ 8 parison (160 cavity)	Process Requirement
Output	19000-20000 Pcs/hr	Process Requirement
Cycle Time	24 sec/cycle	Process Requirement
Filling Range	1 ml to 5 ml	Process Requirement
Type of Material	LDPE	Process Requirement
Plastification Capacity	50-60 Kg/Hr	Process Requirement
Overall Dimensions	6000 mm x 8000mm x 3000 mm	Design Requirement
Total Weight	10.5 tones	Design Requirement
Srew		
Diameter	60 mm x 2 Nos	Design Requirement
Length	L/D 24:1	Design Requirement
Speed	0-75 RPM	Process Requirement
Extruder Motor		
Make	Hindustan	Design Requirement
Type	3 Phase induction motor	Design Requirement
Capacity	20 HP	Design Requirement
Quantity	2 Nos	Design Requirement
Hydraulic Pump Motor		
Make	Hindustan	Design Requirement
Type	3 Phase induction motor	Design Requirement
Capacity	15 HP	Design Requirement
Quantity	2 Nos	Design Requirement
Gear Box		
Make	Form Fill Automation	Design Requirement
Type	Helical	Design Requirement
Ratio	15:1	Design Requirement
Moulds		
Make	Form Fill Automation	Design Requirement



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Critical Variables	Acceptance Criteria	Reference
MOC	Aluminium Bronze	Design Requirement
Mould Clamping Force	Head – 2 Nos , Body – 4 tone	Design Requirement
Pressure Gauges		
Make	Hi- Tech	Design Requirement
Type	Bourdon	Design Requirement
Range	0-2000 PSI	Design Requirement
Quantity		Design Requirement
Pressure Gauges		
Make	SMC	Design Requirement
Range	0-20 Kg	Design Requirement
Quantity		Design Requirement
Pneumatic System Regulators		
Make	SMC	Safety Requirement
Flow Control Valves		
Make	SMC	Safety Requirement
Cylinders		
Make	SMC	Safety Requirement
Solenoid Valves		
Make	SMC	Safety Requirement
Pipe Fittings		
Make	Pheonix	Design Requirement
Electric Heaters		
Make	Form Fill Automation	Design Requirement
Type	Band Heaters with heat insulation	Design Requirement
Quantity		Design Requirement
Hydraulic System Locking Cylinder		
Make	Form Fill Automation	Design Requirement
Stroke	150	Design Requirement
Quantity		Design Requirement
Shifting Cylinder		



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Critical Variables	Acceptance Criteria	Reference
Make	Form Fill Automation	Design Requirement
Stroke	Servo	Design Requirement
Quantity	4 Nos	Design Requirement
Extruder Up Down Cylinder		
Make	Form Fill Automation	Design Requirement
Stroke	75	Design Requirement
Quantity	8	Design Requirement
Pin Up Down Cylinder		
Make	Form Fill Automation	Design Requirement
Stroke	150	Design Requirement
Quantity	4	Design Requirement
Parison Control Cylinder		
Make	Form Fill Automation	Design Requirement
Stroke	40	Design Requirement
Vacuum Gauges		
Make	Hi- Tech	Design Requirement
Type	Bourdon	Design Requirement
Range	0 to -750 mm of WC	Design Requirement
PLC		
Make	Ultra Industries	Design Requirement
VFD		
Make	Teknik	Design Requirement
Pressure Transmitter		
Make	Dawyer	Design Requirement
Model	DW801	Design Requirement
Range	0-1 MPa	Design Requirement
Pressure Gauge		
Make	CATIC	Design Requirement
Location	Primary filter differential pressure	Design Requirement
Range	0-125 Pa	Design Requirement
Make	CATIC	Design Requirement
Location	HEPA filter differential pressure	Design Requirement



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Critical Variables	Acceptance Criteria	Reference
Range	0-500 Pa	Design Requirement
Filtration & Pressure Reducing Valve		
Make	Festo	Design Requirement
Model	DB-7- MINI	Design Requirement
Filters		
Make	Pall	Design & Safety Requirement
Model	0.2 micron	Design Requirement
Quantity	2	Design Requirement
Optical Fiber Sensor		
Quantity	2	
Proximity Switch		
Make	Schneider	Design & Safety Requirement
Qty.	01	Design Requirement
Alarm Light Indicator		
Red Indicator	Machine Stop & Alarm start	Design & Safety Requirement
Orange Indicator	Warning	Design & Safety Requirement
Green Indicator	Machine is working	Design & Safety Requirement
Operating Panel		
Black Switch	On/OFF	Design & Safety Requirement
Green Indicator	Power On/OFF	Design & Safety Requirement
Red Mushroom Button	Emergency Stop	Design & Safety Requirement



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7.1 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material of construction
1.	Machine Frame & Locking Unit	SS304
2.	Manifold	SS316L
3.	Filling unit	SS316L
4.	Filling Nozzle	SS316L
5.	Filling Tank	SS316L
6.	Mould	Pre Hardened Non Corrosive SS
7.	Parison Holder	SS304
8.	Hopper	SS304
9.	Heater	Asbestos



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7.2 SAFETY:

Critical Variables	Specified Function	Reference
Linkage Control	For safety of the equipment & the process.	Safety Requirement
Motor overload	For Motor & equipment protection.	Safety Requirement
Air pressure drop interlock	For safety of the batch & the process.	Safety Requirement
Alarm Indication	For safety of the equipment & the process.	Safety Requirement
Emergency stop	For safety of process & equipment.	Safety Requirement



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7.3 VENDOR SELECTION:

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying FFS Machine.	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical knowledge, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

Reference: (1) Specifications and Requirements as specified in P.O. and URS.

Verified By
(Quality Assurance)
Sign/Date:

9.0 DOCUMENTS TO BE ATTACHED

- Purchase Order Copy.
- Any other relevant documents.



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13.0 ABBREVIATIONS:

CFM	:	Cubic feet per minute
cGMP	:	Current Good Manufacturing Practice
CIP	:	Clean in place
CQA	:	Corporate Quality Assurance
DQ	:	Design Qualification
FFS	:	Form Fill Seal machine
GA	:	General Arrangement
ID.	:	Identification
KG	:	Kilogram
LDPE	:	Low Density Poly ethylene
LPM	:	Liquid per minute
mm	:	Millimeter
NMT	:	Not More Than
No	:	Number
P & ID	:	Piping and Instrumentation Diagram
PLC	:	Programmable Logic Control
PO	:	Purchase Order
RH	:	Relative Humidity
RPM	:	Revolution per minute
SIP	:	Steam in place
SS	:	Stainless Steel
URS	:	User requirement specification



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14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY CONTROL)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			