DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR BLOW FILL SEAL MACHINE LVP LINE

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR BLOW FILL SEAL MACHINE

PROTOCOL CONTENTS

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR BLOW 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)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

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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 **Blow Fill Seal Machine**.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & ID's 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	• Preparation, Compilation Review and Approval 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	• 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	• Review of Design Qualification Protocol cum Report after Execution.
Engineering	• 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. ➢ 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 REQUIRMENT:

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

6.0 BRIEF EQUIPMENT DESCRIPTION:

BFS machine pharmaceutical products are filled aseptically in polyethylene containers by means of the Blow-Fill – Seal technology. The bottle pack filling machine is planned for the filling according to order scope respectively and order confirmation. The subjected bottle pack M/c. function is defining below.

BFS M/C 603 is a compactly built machine for processing of plastic containers in one single process. The feeder supplies plastic granulates to the granule hopper. From hopper the granules fall into the extruder screw. There it is compressed, homogenized by heating, and forced through the extrusion head under pressure. The hot melt plastic leaves the extrusion head in the shape of parison. The speed of the extruder screw controls the discharge speed. Adjustment of the ring-shape nozzle gap changes the parison wall thickness. The parison clamp device clamps the end of the parison and thereby seals it and sterile support air inside the sack prevent sticking together of its walls.

The mould consists of two equal and symmetrical halves along with closing unit.

Each half consist of –

a) Supporting jaw (To hold the parison)

b) Head mould (shaping the container's head)

c) Main mould (shaping the container's body &bottom).

The supporting jaw holds the parison by vacuum. Incandescent cutting knife cut off the parison between the supporting jaw & parison die cup.

Vacuum channel leads to the mould. The plasticized material is attached to the mould cavity with the help of sterile supporting air and vacuum. Then it solidifies & forms the cavity to contain the product and the closing unit moves to filling station. The mandrel comes down and start the filling

of the solution level is continuously maintained in the buffer tank through flow control regulating valve, which is supplied through SS316 pipeline under constant sterile buffer air.

The filling mandrel inside the sterile air moves down into the containers, which are still open on top. The product dose flows in to the containers. The air is expelled from the container escapes through the air outlet channel and the mandrel move up. Then head mould closes and seals the containers.

The hydraulically operated closing unit opens and vials come down on product conveyor. The entire critical components are steam sterilisable with the help of pure steam with an automatically controlled system.

7.0 EQUIPMENT SPECIFICATION:

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

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8.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS/PRODUCT PARAMETERS:

Critical variables	Acceptance criteria	Reference
Application: BFS Machine is used for filling and sealing for liquid Bottle	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 UTILITIY REQUIREMENTS/LOCATION SUITABILITY:

Critical variables	Acceptance criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	Voltage : 380 to 420 V , 3 Phase Frequency : 50 HZ Power : 60 KW Total Load: 150 KW	GMP Requirement
Room Condition	Temperature : NMT 25 ºC RH : NMT 55 %	Process Requirement
Compressed Air(Oil Free)	Pressure : 6-8 bar Capacity : 15-18 CFM	Process Requirement
Pure Steam	30 kg/hr. with pressure at 1.5 – 2.5 Kg/cm.^{2}Purity of steam 1 µm.	
Vacuum	75 CFM at 25-28 HG	Process Requirement
Chilled Water	Temperature : 10°C-12°C Flow Rate : 50 LPM @ 3-4kg/cm^2	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	Weller		Design Requirement
Supplier	Sterimex		Design Requirement
Model	603		Design Requirement
Machine Size	5200mm x 2700mm x 3100mm		Design Requirement
Output	3000 bottles/hr		Process Requirement
Filling Range	100 ml		Process Requirement
Type of Material	LDPE		Process Requirement
Plastification Capacity	50-60 Kg/Hr		Process Requirement
Total Weight	9 tones		Design Requirement
Main Mould			
Make	Sterimax Engineering Pvt. Ltd.		Design Requirement
MOC	Aluminium bronze		Design Requirement
Size	100 ml – 14 cavities.		Process Requirement
Extruder Motor/Drive			
	Motor	**Drive**	Design Requirement
Make	SIMENS	ABB	
Model	1LA0207-4LA80-Z	ACS550-01-059A-4	Design Requirement
Capacity	30 KW	30 KW	Design Requirement
RPM	1470 RPM	0 to 50HZ	Design Requirement
Extruder Gear Box			
Make	Kolellmann Gear		Design Requirement
Ratio	15:1		Design Requirement
Laminar Air LFR motor			
Make	International Portland corporation		Design Requirement
Model	CLASS 10™ Portable clean air station Model 250		Design Requirement
Rating	Class 100		Design Requirement
Size	0.3 µ		
HEPA filter	305mm x 305 mm x 50 mm-0.2µ		Design Requirement

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR BLOW FILL SEAL MACHINE

Critical Variables	Acceptance Criteria	Reference
Efficiency	99.997	Design Requirement
Granule Hopper		
Make	Sterimax Engineering pvt.ltd.	Design Requirement
Material	SS 316L	Design Requirement
Type	Funnel type	Design Requirement
Capacity	40 kg.	Design Requirement
Buffer tank with Load cell		
Make	Sterimax Engineering pvt.ltd.	Design Requirement
Material	SS 316L	Design Requirement
Size	20 Ltr.	Design Requirement
Load cell capacity	250 kg.	Design Requirement
Knife		
Make	Chamunda Engineering Ahmadabad.	Design Requirement
Size	660 X 12 X 2 mm (L x B X T)	Design Requirement
MOC	Nicrome alloy	Design Requirement
Screw cooling unit		
Make	Sterimax Engineering Pvt. Ltd.	Design Requirement
Motor make	Crompton	Design Requirement
Current ratting	2.2 Amp	Design Requirement
voltage	400 volt, 50hz,	Design Requirement
Hydraulic Power Pack		
Motor Make	MARATHON	Design Requirement
Model	3 B 284TTF 08076AA	Design Requirement
HP& Voltage	15 HP , 230/ 460 V	Design Requirement
Speed	1170	Design Requirement
Type	TFC	Design Requirement
Hydraulic Oil Tank		
Make	REXROTH	Design Requirement
Model No.	97730-011196	Design Requirement

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR BLOW FILL SEAL MACHINE

Critical Variables	Acceptance Criteria	Reference
Material	MS	Design Requirement
Capacity	40 Galan	Design Requirement
Hydraulic Cylinder		
Main Mould Hyd. Cylinder LHS	Bore Dia: 2 ½" & Stroke 3"	Design Requirement
Main Mould Hyd. Cylinder RHS	Bore Dia: 2" & Stroke 3"	Design Requirement
Seal Mould Cylinder	Bore Dia: 2" & Stroke 3" Qty: 2 no.	Design Requirement
BWR Hyd. Cylinder	Bore Dia: 1 ½" & Stroke 11".	Design Requirement
Filling Cylinder	Bore Dia: 2" & Stroke 4 ½".	Design Requirement
Extruder lift	Bore Dia: 2 ½" & Stroke 1"	Design Requirement
Vacuum Valve		
Make	Bimba	Design Requirement
Size	25 MM	Design Requirement
Operating	Pneumatic operated.	Design Requirement
Filling Assembly		
Make	Sterimax Engineering pvt. Ltd.	Design Requirement
Material	316L	Design Requirement
Filling system		
Pneumatically operated valve		
Make	Gemo	Design Requirement
Material	Body material – 316L & diaphragm EPDM	Design Requirement
Size	25 mm	Design Requirement
Filling Nozzles	14 Nos.	Design Requirement
Mandrel hood		
Make	Sterimax Engineering Pvt. Ltd. MAHAPE, Mumbai.	Design Requirement
Material	SS 316 L	Design Requirement
Type	Close loop	Design Requirement
Gasket and sealing material		
Materials	Food grade silicon	Design Requirement

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Critical Variables	Acceptance Criteria	Reference
Size	As per requirement	Design Requirement
Aseptic valve		
Make	Steridose	Design Requirement
Materials	SS 316L	Design Requirement
Size	½”& 1”	Design Requirement
Operating range	2 kg to 8 kg/cm2	Design Requirement
Instrumentation		
PLC		
Make	SIEMENS	Design Requirement
Model	SIMATIC S7 - 300	Design Requirement
Input Power	24 V DC	Design Requirement
Output Power	24 V DC	Design Requirement
HMI		
Make	SIEMENS	Design Requirement
Model	MP 377	Design Requirement
Size	15” Touch	Design Requirement
Input Voltage	24 V DC 2.8 A max.	Design Requirement
Proximity switch		
Make	DPM Instrument Pvt ltd.	Design Requirement
Size	M12, 24 V DC	Design Requirement
Qty.	15 Nos.	Design Requirement
Type	PNP NO	Design Requirement
Temperature sensor (SIP)		
Make	DPM Instrument Pvt ltd	Design Requirement
Size	M6 X 50mm Length	Design Requirement
Type	T type	Design Requirement
Qty.	16 no.	Design Requirement
Thermocouple		
Make	DPM Instrument Pvt ltd	Design Requirement

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR BLOW FILL SEAL MACHINE

Critical Variables	Acceptance Criteria	Reference
Size	M6 X 50mm Length	Design Requirement
Type	L type	Design Requirement
Qty.	06 no.	Design Requirement
Pressure gauge for hydraulic oil high pressure		
Make	REXROTH	Design Requirement
Material	SS304	Design Requirement
Size	65MM	Design Requirement
Range	0 to 100 bar	Design Requirement
Pressure gauge for hydraulic oil Low pressure		
Make	REXROTH	Design Requirement
Material	SS304	Design Requirement
Size	65MM	Design Requirement
Range	0 to 100 bar	Design Requirement
Vacuum gauge		
Make	ABP	Design Requirement
Material	SS 304	Design Requirement
Range	0 TO 30 In Hg / 0 to – 760 mmHg	Design Requirement
Size	2”	Design Requirement
Pressure gauge for buffer air		
Make	ABP	Design Requirement
Material	SS 304	Design Requirement
Range	0TO 30 PSI	Design Requirement
Size	4”	Design Requirement
Pressure gauge for buffer air back pressure		
Make	FGB	Design Requirement
Material	SS 304	Design Requirement
Range	0 to 10 kg.	Design Requirement
Size	50 mm	Design Requirement
Product line Pressure gauge		

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Critical Variables	Acceptance Criteria	Reference
Make	FGB	Design Requirement
Material	SS 304	Design Requirement
Range	0 TO 10 Kg	Design Requirement
Size	100 mm	Design Requirement
Type	Diaphragm type glycerin field.	Design Requirement
Qty.	2 no.	Design Requirement
Pressure gauge for pure steam		
Make	ENFM	Design Requirement
Material	SS 304	Design Requirement
Range	0 TO 7 Kg	Design Requirement
Pressure gauge for Blowing Air		
Make	FGB	Design Requirement
Material	SS 304	Design Requirement
Range	0 TO 10 Kg	Design Requirement
Size	50 mm	Design Requirement
Pressure gauge for Support air & Ballooning Air		
Make	FGB	Design Requirement
Material	SS 304	Design Requirement
Range	0 TO 10 Kg	Design Requirement
Size	50 mm	Design Requirement

8.4 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	Aluminum Bronze
7.	Parison Holder	SS304
8.	Hopper	SS304
9.	Heater	Asbestos

8.5 SAFETY:

Critical Variables	Specified Function	Reference
Linkage Control	For safety of the equipment & the process.	Safety Requirement
Safety guard to all moving parts	All moving part should be covered with safety guard.	Safety Requirement
Motor overload	For Motor & equipment protection.	Safety Requirement
Noise Level	Noise level should not more than 90 dB.	Safety Requirement
Vibration	Vibration resistant mounts should be provided.	Safety Requirement
Electrical wiring and Earthing	Double Earthing should be installed to control panel	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

8.6 VENDOR SELECTION:

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying BFS 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.

10.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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11.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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12.0 RECOMMENDATION:

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13.0 ABBREVIATIONS:

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

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR BLOW FILL SEAL MACHINE

14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			