



PHARMA EVILS

QUALITY ASSURANCE DEPARTMENT

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR AMPOULE FILLING AND SEALING MACHINE

**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
AMPOULE FILLING AND SEALING
MACHINE**

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	NIL



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SEALING MACHINE**

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1.0 PROTOCOL PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

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 **Ampoule Filling and Sealing Machine**.
- 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, Review and Approval of the 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 Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review of the 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 Qualification Protocol after Execution.



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5.0 BRIEF EQUIPMENT DESCRIPTION:

Ampoule Filling & Sealing Machine adopts linear intermittent for filling and sealing. The ampoules which come from sterilization and drying tunnel access to infeed Conveying Belt No. 1 via the connection board move to scroll No.2. The scroll will arrange out of order ampoules in separation status, it pushes the ampoules individually to the infeed star wheel No. 4, infeed star wheel No. 4 continuously conveys the ampoules to the walking beam No.5, front walking beam No. 5 can change the continuous movement of ampoules to intermittent movement. The middle walking beam No. 6 can convey the ampoules in a stepping mode to the next station. Ampoule leaning part No. 7 is used for orientation in the static station. The 5 intermittent stations are listed below:

- 1) Front Charging Station**
- 2) Filling Station**
- 3) Rear Charging Station**
- 4) Preheating Station**
- 5) Sealing Station**

Front Charging Station: The front charging station is set with nitrogen gas purging.

Filling Station: At the filling station, rotary piston pump consists of a piece of to and fro rotary valve, a piece of movable piston rod and a piece of pump cylinder the rotary valve is on the upper side of pump cylinder, and it connects with drive group of rotary valve via a stand- alone servo motor via ball screw pair, lifting rod and connection rod. By to and fro movement, the liquid medicine is filled into ampoules by the filling pump.

Rear Charging Station: The rear charging station is set with nitrogen gas purging.

Preheating & Sealing Station: At the preheating station, ampoules are preheated by the nozzle of LPG and Oxygen, and they spin automatically by the idler wheel. At the station of sealing, ampoules are softened by heat and sealed. The sealed ampoules are conveyed through out feed star wheel to Ampoule receiving tray.



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6.0 EQUIPMENT SPECIFICATION:

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

7.0 CRITICAL VARIABLES TO BE MET:

7.1 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

7.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

Critical variables	Acceptance criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	Voltage : 400 V Phase : 3 Phase Frequency : 50 HZ	GMP Requirement
Room Condition	Temperature : NMT 25 °C RH : NMT 55 %	Process Requirement
Gas Pressure (LPG)	0.03Mpa – 0.05 Mpa	Process Requirement
Oxygen Pressure	0.3Mpa – 0.5 Mpa	Process Requirement
Nitrogen Pressure	0.3Mpa – 0.5 Mpa	Process Requirement
Compressed Air Pressure	0.6 Mpa	Process Requirement



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7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

Critical Variables	Acceptance Criteria
Make	Truiking Technology Limited
Model	AGF -12
Overall Dimensions (L x B x H)	3700 mm L x 1840mm H x 2000 mm W
Filling Nozzles	12 Nos.
Main Motor	
Make	Xin Ling
RPM	1410
Power	0.75KW
Infeed Conveying Motor	
Make	ZD
RPM	1350
Power	0.37 Kw
Outfeed Conveying Motor	
Make	ZD
RPM	1350
Power	0.14 Kw
Filling Servo Motor	
Make	Mitsubishi
Model	HG-KR43J
RPM	3000
Power	0.4 Kw
Quantity	17
Ampoule Rotating Motor	
Make	ZD
RPM	90-1350
Power	0.14 Kw
Air Pumping Motor	
Make	Weirkee
RPM	2700



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Critical Variables	Acceptance Criteria
Power	0.22 KW
Starwheel Servo Motor	
Make	Mitsubishi
Power	0.4 Kw
Quantity	4
VFD	
Make	Schneider
Model	ATV12H075M2
PLC	
Make	Mitsubishi
Model	Q173DSCPU
Pneumatic diaphragm valve	
Make	Gemu
Model	650 15D 88 34 5A 1 0T1 1507
Flow meter	
Make	Shuanghuan
Model	LZB-6WB
Quantity	06
Solenoid Valve	
Make	FESTO
Model	MEBH-3/2-1/8-P-B
HMI	
Make	Siemens
Model	6AV7 890-0HB00-0AB0
Pressure Transmitter	
Make	Dawyer
Model	DW801
Range	0-1 MPa
Pressure Gauge	
Make	CATIC
Location	Primary filter differential pressure
Range	0-125 Pa



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Critical Variables		Acceptance Criteria
Make		CATIC
Location		HEPA filter differential pressure
Range		0-500 Pa
Filtration & Pressure Reducing Valve		
Make		Festo
Model		DB-7- MINI
Filters		
Make		Pall
Model		0.2 micron
Quantity		2
Optical Fiber Sensor		
Quantity		2
Proximity Switch		
Make		Schneider
Qty.		01
Alarm Light Indicator		
Red Indicator		Machine Stop & Alarm start
Orange Indicator		Warning
Green Indicator		Machine is working
Operating Panel		
Black Switch		On/OFF
Green Indicator		Power On/OFF
Red Mushroom Button		Emergency Stop
Vertical Laminar Air Flow		
Laminar Flow Hood Size		3234 x 1160 x 350 mm
Motor	Power	2.55 Kw
Hepa Filter	Make	Changyuan
	Size	566 x 979 x 80 mm ,Quantity- 05
		534 x 939 x 80 mm, Quantity- 01
	Porosity	0.3 micron, H14



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Critical Variables		Acceptance Criteria
Pre-filter	Qty.	04
Air Velocity Transmitter		
Make	ELEKTRONIK	
Model	EE660-V7xCxDD/M	
Range	0-2 m/s	

7.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material of construction
1.	Bottom & Top frames	SS-304 Square pipe and angles
2.	Manifold	SS316L
3.	Metals contacting with nitrogen	SS316L
4.	Conveying Belt	SS304
5.	Silicone Pipe	Silicone Rubber
6.	Sealing Clamp	Titanium Alloy
7.	Filling Needles	SS316L
8.	Starwheel , Screw conveyor	POM

7.5 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
Motor overload Relay	For Motor & equipment protection.	Safety Requirement
Alarm Indication	For safety of the equipment & the process.	Safety Requirement



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Emergency stop	For safety of process & equipment.	Safety Requirement
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7.6 VENDOR SELECTION:

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying Ampoule Filling Machine.	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical know how, 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.
(2) Operation manual of Ampoule Filling Machine.

Verified By
(Quality Assurance)
Sign/Date:

8.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Purchase Order Copy.
- Any other relevant documents.



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12.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practice
mm	:	Millimeter
P & ID	:	Piping and Instrumentation Diagram
PO	:	Purchase Order
RH	:	Relative Humidity
SS	:	Stainless Steel
URS	:	User requirement specification
KG	:	Kilogram
AFM	:	Ampoule filling machine
DQ	:	Design Qualification
IB	:	Injection block
No	:	Number
ID.	:	Identification
GA	:	General Arrangement
NMT	:	Not More Than



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13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			