



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AMPOULE FILLING &
SEALING MACHINE**

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



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AMPOULE FILLING & SEALING MACHINE

EQUIPMENT ID. No.	
LOCATION	AMPOULE FILLING & SEALING ROOM
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	NIL

PROTOCOL CONTENTS

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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)			



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AMPOULE FILLING & SEALING MACHINE

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of **Ampoule Filling & Sealing Machine** Model No. **AGF-12** Machine.
- 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 **Ampoule Filling & Sealing Machine** (Model No. **AGF-12**) to be installed in the **Ampoule Filling & Sealing Room**.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Ampoule Filling & Stoppering 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, Approval 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 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 Qualification Protocol after Execution.
Engineering	<ul style="list-style-type: none">• Review & Pre Approval of Protocol cum Report.• Co-ordination, Execution and technical support in VFS Installation Qualification Activity.• Calibration of Process Instruments.• Responsible for Trouble Shooting (if occurs during execution).• Post Approval of Qualification Protocol after Execution.



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5.0 EQUIPMENT DETAILS:

Equipment Name	Ampoule Filling & Sealing Machine
Equipment ID.
Manufacturer's Name	TruKing Technology Limited
Supplier's Name	TruKing Technology Limited
Location of Installation	Ampoule Filling & Sealing Room

6.0 SYSTEM 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 can be set with nitrogen gas purging.



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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.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- Piping and instrumentation diagram (P& ID).
- 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.



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AMPOULE FILLING & SEALING MACHINE

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	Ampoule Filling & Sealing Room		
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 AMPOULE FILLING & SEALING MACHINE

**8.2 EQUIPMENT VERIFICATION:
TECHNICAL SPECIFICATIONS:**

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Model	CFL-120		
Dimensions	2700 mm L x 1800mm H x 1400 mm W		
Main Motor			
Make	Xin Ling		
Model	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	ZD		
Model	HG-KR43J		
RPM	3000		
Power	0.4 Kw		
Quantity	12		
Ampoule Rotating Motor			
Make	ZD		
RPM	90-1350		
Power	0.14 Kw		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Air Pumping Motor			
Make	Weirkee		
RPM	2700		
Power	0.22 KW		
Starwheel Servo Motor			
Make	ZD		
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		
Flowmeter			
Make	Shuanghuan		
Model	LZB-6WB		
Quantity	05		
Solenoid Valve			
Make	FESTO		
Model	MEBH-3/2-1/8-P-B		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
HMI			
Make	Siemens		
Model	6AV7 890-0HB00-0AB0		
Pressure Transmittor			
Make	Dawyer		
Model	DW801		
Range	0-1 MPa		
Pressure Gauge			
Make	CATIC		
Model	YBFMC100		
Range	0-1 MPa		
Filteration & 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		



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Critical Variables		Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
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		
Pre-filter	Porosity	0.3 micron, H14		
Air Velocity Transmitter				
Make		ELEKTRONIK		
Model		EE660-V7xCxDD/M		
Range		0-2 m/s		

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(Manager QA)**



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AMPOULE FILLING & SEALING MACHINE

Sign/Date:

8.3 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.	Get buffer tank nozzles and silicon tubes sterilized before fitting with the machine.		
11.	Clean all the SS guides, bridge plates and star wheel with IP solution.		

Checked By
(Production)

Sign/Date:

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(Quality Assurance)

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AMPOULE FILLING & SEALING MACHINE

Reviewed By
(Manager QA)
Sign/Date:

8.4 MOC Verification List:

Parts Name	Material of construction	Observation	Observed By (Engineering) Sign/Date
Bottom & Top frames	SS-304 Square pipe and angles.		
Manifold	SS316L		
Metals contacting with nitrogen	SS316L		
Conveying Belt	SS304		
Silicone Pipe	Silicone Rubber		
Sealing Clamp	Titanium Alloy		
Filling Needles	SS316L		
Starwheel , Screw conveyor	POM		

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Sign/Date:



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8.5 Utility Verification List:

Critical variables	Acceptance criteria	Observation	Observed By (Engineering) Sign/Date
Electrical Supply	Voltage : 400 V Phase : 3 Phase Frequency : 50 HZ		
Room Condition	Temperature : NMT 25 °C RH : NMT 55 %		
Gas Pressure (LPG)	0.03Mpa – 0.05 Mpa		
Oxygen Pressure	0.3Mpa – 0.5 Mpa		
Nitrogen Pressure	0.3Mpa – 0.5 Mpa		
Compressed Air Pressure	0.6 Mpa		

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Sign/Date:

8.6 Safety:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Hardware Emergency switch at Operator Console	For Operator Safety.		
Nitrogen pressure drop interlock	For safety of the batch		
Liquid low level – Machine stop	For safety of the batch & the process.		
Motor overload Relay	For Motor & equipment protection.		
No Ampoule 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 any sharp edges.		
Leveling And Balancing	Equipment should be properly balanced & leveled		
Electrical Wiring And Earthing	Electrical wiring should be as per approved drawings. Double external Earthing to control machine (Panel and Motors) and operator should be provided		
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.		
Mechanical Safety Clutch	Provided with gear box		
All Drive Arrangements	With all covers and guards		



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Reviewed By
(Manager QA)
Sign/Date:

8.7 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
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Sign/Date:

Verified By
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(Manager QA)
Sign/Date:



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AMPOULE FILLING & SEALING MACHINE

9.0 REFERENCES:

- Design Qualification.
- Operation and Maintenance Manual

10.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC.
- Calibration certificates.
- Operation and Maintenance Manual.

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):



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AMPOULE FILLING & SEALING MACHINE

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AMPOULE FILLING & SEALING MACHINE

16.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practice
CQA	:	Corporate Quality Assurance
mm	:	Millimeter
MOC	:	Material of Construction
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
IQ	:	Installation Qualification
IB	:	Injection block
No	:	Number
ID.	:	Identification
GA	:	General Arrangement
AC	:	Alternating Current
CQA	:	Corporate Quality Assurance
NLT	:	Not Less Than
NMT	:	Not More Than
Db	:	Decibel



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AMPOULE FILLING & SEALING MACHINE

17.0 PROTOCOL POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

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HEAD (QUALITY ASSURANCE)			



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