



**FACTORY ACCEPATANCE TEST
OF
AGF12 AMPOULE FILLING AND SEALING
MACHINE**

LOCATION	AMPOULE LINE
SUPERSEDES No.	NIL



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QUALITY ASSURANCE DEPARTMENT

FAT FOR AMPOULE FILLING & SEALING MACHINE

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1.0 APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (USER DEPARTMENT)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



FAT FOR AMPOULE FILLING & SEALING MACHINE

2.0 PURPOSE:

- To ensure that the AGF12 Ampoule Filling and Sealing Machine manufactured by M/s Truking Technology Limited is manufactured as per design specification.
- The machine is performing as per agreed performance specification at manufacturer's site.

3.0 SYSTEM OVERVIEW:

AGF12 ampoule filling and sealing machine is used in ampoule filling and sealing in Pharmaceutical and chemical industries. This machine can be used individually, or can be used in a compact line with other single units. The equipment should be installed at the Class B cleaning room with partial Class A cleaning spaces in the main equipment workshop. The main component parts of the equipment include: body, net belt for ampoule infeed, gas pipelines, filling unit and electric control cabinet including operational panel.



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4.0 EQUIPMENT COMPONENTS / BOUGHT OUTS:

S.No.	Component	Expectation	Actual	Remarks
1.	Machine	AGF12 Ampoule Filling Machine.		
2.	Make	Truiking		
3.	Two way tee solenoid valve (normally closed)	Make :FESTO) Model: MEBH-3/2-1/8-P-B		
4.	Flowmeter	Make : (Shuanghuan, Model: LZB-6WB		
5.	Filtration and pressure reducing valve	Make : (FESTO) Model: LFR-1/4-DB-7-MINI		
6.	Pneumatic diaphragm valve	Make : GEMU Model: 650 15D 88 34 5A 1 0T1 1507		
7.	Gas solenoid valve	PU220-04A		
8.	Solenoid valve	2W-160-15		
9.	Servo motor	<ul style="list-style-type: none">Brand: MitsubishiModel : HG-KR43JPower Consumption : 0.4KWQty.:17		
10.	Transducer	<ul style="list-style-type: none">Brand: SchneiderModel : ATV12H075M2Parameters :single phase 200-240V/0.75KWQty.:01		
11.	PLC	<ul style="list-style-type: none">Brand: MitsubishiModel: Q173DSCPUParameters: 32 axes motion controller built-in encoder interface and battery		
12.	Touch screen	<ul style="list-style-type: none">Brand: SiemensModel : 6AV7 890-0HB00-0AB0Man parameters 12''Qty.01		
13.	The metal material contacting with the liquid medicine, e.g., filling needle	MOC : SS316L		
14.	Sealing clamp	MOC : Titanium alloy		



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S.No.	Component	Expectation	Actual	Remarks
15.	Silicone pipe	MOC : Silicone rubber		
16.	Starwheel, screw conveyor and barrier, etc.	MOC : POM		
17.	Other exposed components of equipment	MOC : SS304		
18.	Manifold	MOC : SS316L		
19.	Conveying belt	MOC : SS304		
20.	Non-metal material contacting with the liquid medicine	MOC :Silicone rubber		
21.	The metal material contacting with nitrogen, etc.	MOC : SS316L		
22.	TECHNICAL PARAMETERS			
	Production capacity	0~24000pcs/h (1ml)		
	Ampoule breakage rate	≤0.1%		
	Qualified sealing rate	≥99%		
	Rate of no ampoule no filling	100 %		
	Compressed air pressure	0.6Mpa		
	Gas consumption and Pressure	0.03-0.05MPa, 0.6m3/h		
	Oxygen consumption and pressure	0.3-0.5MPa, 1.8m3/h		
	Nitrogen consumption and pressure	0.3-0.5MPa, 2m3/h		
	Filling precision	Accord with the requirements of Pharmacopoeia		
	Power capacity	10.6KW		



FAT FOR AMPOULE FILLING & SEALING MACHINE

5.0 TEST & CHECKS:

5.1 VERIFICATION OF FILLING MACHINE SPEED:

- The test should be carried out for each size of Ampoule
- Run the machine at a particular speed for 60 min.
- Check that machine speed synchronize with Liquid filling assembly speed.
- Observed the following parameters in below for each Size of Ampoules i.e. 1 ml, 2 ml, 3 ml & 5 ml Ampoules.

S.No.	Parameters to be observed
1.	Ampoules Breakage
2.	Machine jam/ Held up
3.	Scratching of Ampoules surfaces
4	Falling of Ampoules

- **Acceptance Criteria:** Filling Machine should run at 80 % Speed of designed speed
- Record the results in **Annexure: I**

5.2 TEST FOR FILL VOLUME VARIATION & PARTICULATE MATTER

- The test should be carried out for each size of ampoules
- Perform the test for 1 ml , 2 ml, 3ml, & 5 ml ampoule size
- Switch “ON” the machine.
- Note down the number of each ampoule filled by each needle. run the machine at Particular speed for 60 min.
- Collect the ampoules after filling note down the fill volume of these Ampoules.
- **Acceptance Criteria:**
 - Filling Machine should deliver the liquid in each ampoule as per standard filled Volume.
 - After filling Particulate matter test: Ampoules should be filled with water for injection and afterward be inspected on the contamination with visual inspection booth.
 - Record the results in **Annexure: II.**

5.3 TEST FOR SEALING QUALITY:

- The test should be carried out for each size of ampoules
- Carry out the test simultaneously.
- Load the filling & sealing Machine with the ampoules.
- Switch “ON” the machine & Operate.
- Collect the ampoules and Carry out the leak test& physical appearance.



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- **Acceptance Criteria:**

Filled ampoule should be passed in leak tester machine.

- Record the results in **Annexure: III**



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ANNEXURE I

VERIFICATION OF FILLING MACHINE SPEED

Date of test		Machine Speed	
Product Name			
Ampoule Size			

Parameter	Low Speed ()	Optimum Speed ()	High Speed ()
Sample after(min)			
Ampoule Breakage			
Machine jam			
Scratching of Ampoules surfaces			
Falling of Ampoules			
Rejection(B1)(B2)(B3)
Sample after(min)			
Ampoule Breakage			
Machine jam			
Scratching of Ampoules surfaces			
Falling of Ampoules			
Rejection(B1)(B2)(B3)
Sample after(min)			
Ampoule Breakage			
Machine jam			
Scratching of Ampoules surfaces			
Falling of Ampoules			
Rejection(B1)(B2)(B3)
Total rejection	$\Sigma B1=$	$\Sigma B2=$	$\Sigma B3=$

- **Acceptance Criteria:** Filling Machine should run at 80 % Speed of designed speed.



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ANNEXURE II

TEST FOR FILL VOLUME VARIATION

	Filling volume in ml												Checked by
	1	2	3	4	5	6	7	8	9	10	11	12	
Initial													
Middle													
End													

ACCEPTANCE CRITERIA: Filling Machine should deliver the liquid in each ampoule as per standard filled Volume.

AFTER FILLING & SEALING PARTICULATE MATTER TEST

	FILLING HEADS												Checked by
	1	2	3	4	5	6	7	8	9	10	11	12	
Black particle													
Glass particle													
foreign particle													

ACCEPTANCE CRITERIA: Filled Ampoule should be free from foreign particle/white /black Particles.



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	SEALING QUALITY												Checked by
	1	2	3	4	5	6	7	8	9	10	11	12	
Initial (OK/ Not OK)													
MIDDLE (OK/ Not OK)													
END (OK/ Not OK)													

ACCEPTANCE CRITERIA: Ampoule Sealing should be passed in leak test.



FAT FOR AMPOULE FILLING & SEALING MACHINE

6.0 OPERATIONAL CONTROL FUNCTION CHECKS:

S.No.	Operation	Observation	Remarks
1.	Take trial of the machine on the site by operating the machine with 1 ml, 2 ml 3 ml, 5 ml & 10 ml glass ampoule).		
2.	Linkage control: 1) PC safety door is interlocked. When it is opened, the machine stops. 2) When LF stops, the machine stops; when the machine stops, but LF doesn't stop. 3) When ampoules cram for the tunnel, the washing machine stops.		
3.	Alarm and indication : 1) Air pumping motor overload 2) Zero speed of machine. 3) Ampoule absent for the conveying belt in the inlet 4) LF overload. 5) Servo ready		
4.	Control : 1) During production, input batch number, specification and product name, etc. into the automatic interface. Touch the button "start/stop" gently, revolve the knob of speed adjustment slowly, the filling and sealing machine starts working. 2) Machine should not make any abnormal sound or vibration during operation: MMI & PLC support should be available During Auto operation. 3) Before starting the Ampoule filling machine the PLC should require to enter the Product, Batch Number by the Operator.		



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7.0 OBSERVED DEVIATIONS/DISCUSSIONS:

8.0 RECOMMENDATION:

9.0 CONCLUSION:



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FAT CARRIED OUT BY:	MANUFACTURER
Sign. _____ Date : _____	Sign. _____ Date : _____
Name : _____	Name : _____
Sign. _____ Date : _____	Sign. _____ Date : _____
Name : _____	Name : _____
Sign. _____ Date : _____	Sign. _____ Date : _____
Name : _____	Name : _____

10.0 DOCUMENTS:

- All MOC Certificates, Manual for Bought out items
- Design Qualification protocol.
- Installation Qualification protocol.
- Operational Qualification protocol.
- Schematic Diagram of machine showing Overall Dimensions.
- Instrument list with manufacturer's calibration certificate.
- Electrical unit Diagram.
- P & ID Diagram / G.A Drawing.
- Operating & Service Manual
- Spare Part List.



FAT FOR AMPOULE FILLING & SEALING MACHINE

11.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practices
cGEP	:	Current Good Engineering Practices
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
MOC	:	Material of Construction
SS	:	Stainless Steel
WHO	:	World Health Organization
mm	:	Millimeter
WG	:	Water Gauge
Hz	:	Hertz
V	:	Volt
Cu	:	Copper
Al	:	Aluminum
POM	:	Polyoxymethylene
SS	:	Stainless Steel
FAT	:	Factory Acceptance Test