

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOMATIC CAPSULE FILLING

MACHINE

EQUIPMENT ID. No.	
LOCATION	Capsule Filling
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



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PRE – APPROVAL: 1.0

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANGER (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



2.0 **OBJECTIVE:**

- To provide documented evidence for the Installation Qualification of Automatic Capsule Filling 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 • Automatic Capsule Filling Machine (Make – anchor mark) to be installed in the Capsule filling.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Automatic Capsule Filling Machine.

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	Initiation, Authorization, Approval and Compilation of the Installation
	Qualification Protocol cum Report.
	• Co-ordination with Production and Engineering to carryout Qualification activity.
	Monitoring of Installation Qualification Activity.
Production	Review Pre & post Approval of Protocol cum Report.
	• To Co-ordinate and support for Execution of Qualification study as per Protocol.
Engineering	Review Pre & post Approval of Protocol cum Report.
	• Co-ordination, Execution and technical support in Automatic Capsule Filling
	Machine Installation Qualification Activity.
	Calibration of Process Instruments.
	• Responsible for Trouble Shooting (if occurs during execution).



5.0 EQUIPMENT DETAILS:

Equipment Name	Automatic Capsule Filling Machine.	
Equipment		
Manufacturer's Name	Anchor mark private limited	
Model	PHARMAFILL A120	
Supplier's Name		
Location of Installation	Capsule filling	

6.0 SYSTEM DESCRIPTION:

The entire equipment can be classified into two zones production zone and non-production zone:

6.1 **Production Zone**

- The production zone encompasses the upper portion of the Capsule Filling Machine and is enclosed by the acrylic doors followed by interlock system.
- The production zone includes the loader assembly, powder assembly with rejection system, unseparated capsule rejection assembly, locking assembly, ejection assembly and turret assembly.
- The loader assembly consists of the loader body with magazine & finger block assembly, raceway and pusher block. The capsules descend from magazine onto the slots of the raceway and the pusher block then orients the capsules on the raceway. The finger block then releases the capsule with cap up and body down position.
- The powder assembly consists of the tamping punches, punch guide plate, scrapper plate, dosing disc with drum. The dosing disc is indexed with six station indexers. The tamping pins are used to tamp the powders at the 5 stations and at the 6th station the slug is ejected out into the body of the capsule placed in the bottom segment.
- The rejection assembly consists of the rejection bracket that reciprocates on every stroke of the machine. The rejection bracket aids in raising the un-separated capsule. The capsules are then sucked by means of the vacuum blower.
- Locking assembly consists of locking pins that reciprocate on every stroke of machine. The pins are used to lock the filled capsules against fixed plate on the opposite side.
- The ejection assembly consists of the ejection pins that reciprocates on every stroke of the machine and ejects the filled capsule into the outlet chute with blow of pneumatic air.
- The turret assembly consists of turret, top cam, bottom cam, top segment and bottom segment. The turret is driven by the twelve-station indexer.

The following operations are performed at each station



- Station for loading and separation of the capsules (ROW 2)
- Upward movement of the top segment and backward movement of the bottom segment
- Station for filling Pellet / Tablet into the capsule
- Station for filling powder into the capsule
- Station for filling Pellet / Tablet into the capsule
- Station for rejecting the un-separated capsules
- Downward movement of the top segment and forward movement of the bottom segment
- Station for locking the capsule
- Station for idle station
- Station for ejecting the capsule
- Station for cleaning the segments

6.2 Non-Production Zone

- The non-production zone encompasses the lower portion of the machine and is enclosed within the SS panel sheets. It also includes the area above the production zone of the machine
- The non-production zone includes the entire drive assembly. The drive assembly consists of the brake motor & gearbox assembly connected to the main shaft via chain & sprocket assembly.
- The cams for the respective stations are mounted on the main shaft and the drive to the station is through cam follower, lever and tie rod attached to the assembly in the production zone.
- The 12-station indexer for turret and 6 station indexers for powder filling assembly is located in the non-production zone at the bottom side of the top plate. The drive to the indexer from the main shaft is through separate chain & sprocket arrangement.
- The electrical control panel is placed separately in the Capsule filling room beside the main machine. It includes the MCB, contactors, O/L relay, PLC, relay card, VFD, SMPS terminals etc
- The drive to the powder hopper assembly to stirrer is from the separate motor & gearbox assembly. The motor & gearbox assembly is placed in the area below the production zone.

6.3 Pellet / Granule filling attachment (2 Nos.)

The Pellet feeding assembly consists of the Pellet hopper, dosage adjustment block, dosage adjustment finger plate and lower fixed block. The Pellets are transferred from Pellet hopper into the dosage adjustment block through Pellet hopper discharge pipe. The sliding plate is reciprocated by means of the cam lever mechanism which delivers the Pellets into the capsule body. Amount of dosage can be varied with the dosage adjustment finger plate.



Machine will be supplied with 1 No. of pellet filling attachment each for capsule size #0 & capsule size #3

6.4 Tablet filling attachment (2 Nos.)

The tablet feeding assembly consists of the vibratory bowl, magazine, sliding plate and lower fixed block. The tablets are oriented and transferred into the magazine from the vibratory bowl. The tablets are then transferred into the lower fixed block through the reciprocating action of the sliding plate. The sliding plate is reciprocated by means of the pneumatic cylinder arrangement. Tablet filling attachments for capsule size #0 will be fits either side of the powder filling station.

Machine is provided with the special feature of rejecting the single capsule for No Tablet filling & if the 5 capsules are observed continuously without tablet machine will stop. These will give exact the quantity of capsule rejected due to NO Tablet Filling.

6.5 **Control System**

The Control system for the equipment is a standard control based system. Control panel with all related electrical and pneumatic components is provided separately from main machine. The Operating panel cum control panel provided is of SS 304 in construction.

PRE – QUALIFICATION REQUIREMENTS: 7.0

7.1 **Verification of Documents:**

- Executed and approved design qualification document.
- Piping and instrumentation diagram (P& ID).
- Technical specification of equipment. ٠
- 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.



PHARMA DEVILS

8.0 CRITICAL VARIABLES TO BE MET:

8.1 GENERAL CHECKS AND LOCATION SUITABILITY:

Installation Checks	Acceptance Criteria	Observation
Grouting And Mounting	Should be grouted & mounted properly.	
Leveling	The equipment should be balanced and leveled	
	properly.	
Edges of parts	All the edges of metal parts should be grinded and no	
	sharp edges should be there.	
Welding of Joints	The welding joints should not have any burrs.	
Place of Installation	Capsule filling	
Illumination in area	NLT 300 Lux.	
Working space around	Should be sufficient for easy operation, cleaning,	
the equipment	sanitation and maintenance.	

Checked By Sign & Date: Verified By Sign & Date:

8.2 PRELIMINARY CHECK LIST – OVERALL CONDITION:

S.No.	Checks to be performed:	Observation
1.	Check for the overall dimensions	
2.	Check for the receipt of the consignment with reference to the packing list	
3.	Check for the horizontal leveling and proper positioning of the equipment	
4.	Check for scratches on the machine body	
5.	Check for the condition of the acrylic door.	
6.	Check for the dents on the pillars and the side covers of the machine body.	
7.	Check for the condition of the filter bag in the vacuum filter tank	
8.	Check for the condition of the filter bag in de-dusting filter tank	

Checked By Sign & Date: Verified By Sign & Date:



8.3 COMPONENT LOCATION LIST:

S.No.	Component	Location	Observation
Mech	anical	1	
1.	Main motor	Inside machine stand	
2.	Main motor gearbox	Inside machine stand	
3.	Cams & levers for loader, rejection, ejection assemblies etc	Inside the machine stand	
4.	Indexer for turret drive	Inside the machine stand	
5.	Turret assembly consisting of top cam & bottom cam with top & bottom segment	Assembled on the machine top plate	
6.	Loader assembly consisting of magazine, capsule release blade, raceway, pusher block and finger bag	Assembled on the machine top plate	
7.	Rejection bracket assembly	Assembled on the machine top plate	
8.	Ejection pin assembly	Assembled on the machine top plate	
9.	Capsule hopper	Assembled on the machine top plate	
10.	Vacuum pump motor	Assembled to the vacuum pump	
11.	Blower motor	Assembled to the Blower	
12.	Powder filling assembly	Assembled on the machine top plate	
13.	Tablet Station 1 assembly	Before Powder Filling station	
14.	Tablet station 2 assembly	After powder filling station	
15.	Pellet filling assembly	After powder filling station	
Elect	rical		
1.	MCB for Main Motor	Inside Electrical Control Panel.	
2.	MCB for control circuit	Inside Electrical Control Panel.	
3.	MCB for Vacuum pumps & Blower	Inside Electrical Control Panel.	
4.	Contactor for vacuum pump motor	Inside Electrical Control Panel.	
5.	Contactor for blower motor	Inside Electrical Control Panel.	
6.	Contactor for powder auger motor	Inside Electrical Control Panel.	
7.	Overload relay for vacuum pump	Inside Electrical Control Panel.	
8.	Overload relay for blower motor	Inside Electrical Control Panel.	
9.	Overload relay for powder auger motor	Inside Electrical Control Panel.	
10.	PLC	Inside Electrical Control Panel.	
11.	Add on Digital Input & Digital Output cards	Inside Electrical Control Panel.	



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S.No.	Component	Location	Observation
12.	SMPS	Inside Electrical Control Panel.	
13.	Phase failure	Inside Electrical Control Panel.	
14.	Brake contactor	Inside Electrical Control Panel.	
15.	Relay Cards	Inside Electrical Control Panel.	
16.	VFD for main motor	Inside Electrical Control Panel.	
17.	Emergency Push Button	Operating Panel	
18.	HMI	Operating panel	
19.	Inductive sensor	Inside the machine stand & above the machine stand	
20.	Capsule level sensors	Fit With the capsule hopper	
21.	Powder Sensor	On the Powder hopper	
22.	Tablet sensors	Fit with tablet magazine at station 1 & 2	
23.	Pellet sensor	Fits on the pellet hopper	
24.	Vibrator controller	Fit with panel inside the drive unit	
Pneur	natic		
1.	Digital pressure switch for Main air pressure	Pneumatic panel plate inside the drive unit	
2.	Digital pressure switch for vacuum pressure	Operating Panel	
3.	Actuating Cylinder for capsule loader	On the capsule loader	
4.	Actuating Cylinder for Tablet station	Fit with tablet assembly station 1 & station 2	
5.	Actuating Cylinder for sampling with ejection chute	On the ejection chute.	
6.	FR Unit	On the machine back panel	
7.	Solenoid Valves	On the pneumatic plate	
8.	Solenoid Coils	On the solenoid valves	
9.	Silencers	On the manifold	
10.	Manifold	On the pneumatic plate	



8.4 DETAILED COMPONENT CHECK LIST – PHYSICAL SPECIFICATION:

S.No.	Component Description	Specification	Observation
Mecha	nical		
1.	Main motor	Make- Bonfiglioli, 1430RPM, 2 HP, 415 V, 50 Hz	
2.	Main gearbox	Make- Bonfiglioli, Model - AS25 P P90	
3.	Powder feeder motor	Make- Bonfiglioli, BN71B4, 0.5 HP, 415 V, 50 Hz,1397 RPM	
4.	Powder feeder gearbox	Make- Bonfiglioli, Ratio-28:1 Model - VF49FA228P71B5B3	
5.	De-dusting blower	Make- Minivac, Model - SVR-200	
6.	De-dusting blower motor	Make- Hindustan Motor, 5 HP, 2900 RPM, 415 V, 50 Hz	
7.	Vacuum Pump-1	Make- Minivac, Model - SVL 1000,	
8.	Vacuum pump 1 motor	Make- Hindustan, 3 HP, 415 V, 50 Hz, 1440 RPM	
9.	Vacuum Pump-2	Make- Minivac, Model - SVL 1000,	
10.	Vacuum pump 2 motor	Make- Hindustan, 3 HP, 415 V, 50 Hz,1440 RPM	
11.	Vacuum tank filter bag	Material – 100% cotton	
12.	De-dusting tank filter bag	Material – PC Satin	
Electri	cal		
1.	MCB for Main Motor	Make – Schneider, 10A, 3 poles	
2.	MCB for control circuit, PLC, SMPS	Make – Schneider, 6 A, 2 poles	
3.	MCB for Vacuum Blower & Accessories	Make – Schneider, 32 A, 3 poles	
4.	VFD for Main motor	Make – Mitsubishi, Model – FR-D740-036-E16	
5.	Contactor for vacuum pump (2 Nos)	Make – Siemens, 3TF30, 10E	
6.	Contactor for de-dusting blower	Make – Siemens, 3TF30, 10E	
7.	Contactor for powder feeder motor	Make – Siemens, 3TF30, 10E	
8.	Overload relay for vacuum pump (2 nos.)	Make – Siemens, 3.2 - 5 A	



PROTOCOL No.:

Specification	

S.No.	Component Description	Specification	Observation
9.	Overload relay for de-dusting blower	Make – Siemens, 5 - 8 A	
10.	Overload relay for powder feeder motor	Make – Siemens, 0.63-1 A	
11.	Brake Contactor	Make- GIC	
12.	Relay Cards (02nos.)	Make – Shavison Electronics, 8 Way	
13.	SMPS	Make – Omron, Model: S8VKC06024	
14.	PLC	Make – Mitsubishi, Model – FX 3GE-40M	
15.	Add on cards	Make – Mitsubishi, Model – FX2N-16EX (3 Nos.) FX2N-16EYT (2 Nos)	
16.	HMI	Make – Beijer, Model – X2 base	
17.	Emergency P/B	Make – Teknic	
18.	Control ON/OFF Switch	Make – Teknic	
19.	Buzzer	Make - Sumo	
20.	Inductive sensor	Make – Omron	
21.	Capacitive sensor	Make – IFM Sensor	
22.	Capsule level sensor	Make – Sick,	
23.	Tablet Sensor	Make - Panasonic	
24.	Pellet level sensor	Make – Sick, CM18-12NPP-EC1 (1 No.)	
25.	Door sensor	Make – Sick, RE11-SAC & RE11 (08 Nos.)	
26.	Main Switch	Make – L & T Salzer, 24V DC	
Pneum	atic		
1.	Digital Pressure switch for Main air pressure	Make – Panasonic	
2.	Digital pressure switches for vacuum. (2 Nos)	Make – SMC, Model: ZSE 30	
3.	Actuating Cylinder (Ejection chute)	Make – SMC, Model: CJ2B-16-25Z, 16 mm bore x 25 mm stroke	
4.	Actuating Cylinder (Loader)-2 nos.	Make – CKD Model: SSD-D-12-5	
5.	Actuating Cylinder (Tablet Assembly) - 2 nos.	Make – Festo, Model: AND-20-10-A-P-A	



PROTOCOL No.:

S.No.	. Component Description Specification		Observation
6.	Tablet unfilled capsule rejection solenoid valve with flow controller	Make – Festo, Model – VUVG-L14-T32C-MT- G18-1P3	
7.	Tablet cylinder actuating solenoid valve	Make – Festo, Model – VUVG-L14-T32C-MT- G18-1P3	
8.	FR Unit	Make – Festo, Model: LFR– D – Mini, Filter Regulator	
9.	Solenoid Valves-5 nos	Make – SMC Pneumatics SY5120-4-LZ-01	
10.	Manifold	Make – SMC Pneumatics	
11.	Silencers	Make – SMC Pneumatics	
12. Tubings		Make – SMC Pneumatics, PU6 & PU8	

Checked By Sign & Date:

Verified By Sign & Date:

8.5 MATERIAL OF CONSTRUCTION:

S. No.	Components	Material of Construction (MOC)	Observation
1.	Powder Hopper	MOC Certificate	
2.	Stirrer	MOC Certificate	
3.	Powder outlet pipe	MOC Certificate	
4.	Powder drum	MOC Certificate	
5.	Scrapper block	MOC Certificate	
6.	Scrapper holding plate	MOC Certificate	
7.	Dosing disc	MOC Certificate	
8.	Tamping punch	MOC Certificate	
9.	Top segment	MOC Certificate	
10.	Bottom segment	MOC Certificate	
11.	Pellet Hopper	MOC Certificate	
12.	Pellet Discharge Pipe	MOC Certificate	

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8.6 VERIFICATION OF TEST CERTIFICATES:

S.No.	Component	Type of Certificate	Observation
1.	Main motor	Test Certificate	
2.	Main motor gearbox	Test Certificate	
3.	Powder motor	Test Certificate	
4.	Powder motor gearbox	Test Certificate	
5.	Vacuum pump	Test Certificate	
6.	Vacuum pump motor	Test Certificate	
7.	Blower	Test Certificate	
8.	Blower motor	Test Certificate	
9.	Powder sensor	Test Certificate	
10.	Capsule sensors	Test Certificate	
11.	pellet sensor	Test Certificate	
12.	Tablet Sensors	Test Certificate	
13.	Main Air Pressure switch	Test Certificate	

Checked By Sign & Date:

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8.7 POWER AND UTILITY CHECKLIST:

Sr. No.	Utility Parameter	Method of verification	Acceptance Criteria	Observation
1.	Phase	Visual Check	3 Phase	
2.	Voltage Test	R¥Y	$415\pm10\%$	
	(Using Multimeter)	Y¥B	$415\pm10\%$	
		R ¥ B	$415\pm10\%$	
3.	Frequency	Multimeter	50 Hz	

Inference:

Reviewed By Sign & Date:



9.0 **REFERENCES**:

The Principle Reference is the following:

- Validation Master Plan
- Schedule-M "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2 Good Manufacturing Practices and Inspection.

10.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC
- Calibration certificates

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

12.0 CHANGE CONTROL, IF ANY:

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



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15.0 **RECOMMENDATION:**

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16.0	ABBREVIA	FIONS :	
	PVT.	:	Private limited
	LTD.	:	Limited
	IQ.	:	Installation Qualification
	BOF.	:	Brought out of items
	URS.	:	User Requirement Specification
	MCB	:	Miniature Circuit Breaker
	VFD	:	Variable Frequency Drive
	SMPS	:	Switched mode power Supply
	MOC	:	Material of Construction
	NOS	:	Numbers
	NLT	:	Not less than
	NMT	:	Not more than
	°C	:	Temperature
	RH	:	Relative Humidity
	LPM	:	Liter per minutes
	Kg.	:	Kilo gram
	GMP	:	Good Manufacturing Practice
	Р.О.	:	Purchase Order
	Hz	:	Hertz
	H.P.	:	Horse Power
	A.C.	:	Alternating Current
	V	:	Voltage

- RPM Rotation per Minute :
- Millimeter mm :
- S.S. Stainless Steel : MOC Material of Construction : General Arrangement GA :
- Piping and Instrumentation Diagram P & ID :
- M. S. Mild Steel :
- Programmable logical controller PLC :



POST APPROVAL: 17.0

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			