



PHARMA DEVILS

**INSTALLATION QUALIFICATION PROTOCOL  
FOR  
AUTOMATIC CAPSULE FILLING MACHINE WITH POWDER,  
PELLET AND TABLET FILLING ATTACHMENT**

**PROTOCOL No.:**

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**1.0 SYSTEM INFORMATION**

<b>Manufacturer</b>	<b>Regd. Office: -</b>	<b>Works: -</b>
<b>Customer</b>		
<b>Site</b>		

**Protocol Prepared By**

<b>Name of the Manufacturer</b>	<b>Signing Authority &amp; Designation</b>	<b>Signature</b>	<b>Date</b>

**Protocol Approved By**

<b>Name of the Customer</b>	<b>Signing Authority &amp; Designation</b>	<b>Signature</b>	<b>Date</b>



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**2.0 OBJECTIVE**

- 2.1. The Installation Qualification Protocol (hereafter referred to as 'IQ') shall verify the static attributes of the equipment Automatic Capsule Filling Machine With Powder, Pellet And Tablet Filling Attachment (Hereafter referred to as 'A120') being manufactured by .....for .....
- 2.2. This protocol shall confirm that the machine manufactured, complies with the specifications laid down in this protocol.

**3.0 SCOPE**

- 3.1. The scope of this IQ shall be confined to Pharmafill A120.
- 3.2. The Qualification of any additional accessories apart from those specified in this IQ shall not be in the scope of this document.
- 3.3. The Qualification of the support utilities shall not be in the scope of this IQ.
- 3.4. The equipment shall be intended for filling powder, Pellets & tablets into the hard gelatin capsules.
- 3.5. The equipment shall operate in a dust-free environment with humidity in the range 35 – 45 %RH and temperature in the range of 20 – 25° C

**4.0 RESPONSIBILITIES**

**4.1 Manufacturer**

- 4.1.1 To ensure that the equipment manufactured is in line with the DQ.
- 4.1.2 To prepare the IQ incorporating the following major parameters:
  - Check list for all bought-out items
  - Verification of MOC Certificates and Test certificates in reference to DQ
  - Verification of the required utilities in line to the DQ.
- 4.1.3 To assist the Customer to carry out the IQ at the Installation site.

**4.2 Customer**

- 4.2.1 To carry out the IQ at the Installation site.
- 4.2.2 To verify the IQ.
- 4.2.3 To approve the IQ.



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**5.0 PRELIMINARY CHECK LIST – OVERALL CONDITION**

S.No.	Checks to be performed:	Observation	Remarks
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		

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### 6.0 COMPONENT LOCATION LIST

S.No.	Component	Location	Observation (Physical Condition)	Remarks
<b><u>Mechanical</u></b>				
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		
<b><u>Electrical</u></b>				
1.	MCB for Main Motor	Inside Electrical Control Panel.		
2.	MCB for control circuit	Inside Electrical Control Panel.		
3.	MCB for Vacuum	Inside Electrical		



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S.No.	Component	Location	Observation (Physical Condition)	Remarks
	pumps & Blower	Control Panel.		
4.	Contactora for vacuum pump motor	Inside Electrical Control Panel.		
5.	Contactora for blower motor	Inside Electrical Control Panel.		
6.	Contactora 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.		
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		

**Pneumatic**



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S.No.	Component	Location	Observation (Physical Condition)	Remarks
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		



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**7.0 DETAILED COMPONENT CHECK LIST – PHYSICAL SPECIFICATION**

S.No.	Component Description	Specification	Observation	Remarks
<b><u>Mechanical</u></b>				
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		
<b><u>Electrical</u></b>				
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		





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S.No.	Component Description	Specification	Observation	Remarks
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		
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		



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S.No.	Component Description	Specification	Observation	Remarks
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		

**Pneumatic**

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		
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		



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S.No.	Component Description	Specification	Observation	Remarks
10.	Manifold	Make – SMC Pneumatics		
11.	Silencers	Make – SMC Pneumatics		
12.	Tubings	Make – SMC Pneumatics, PU6 & PU8		



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**8.0 MOC VERIFICATION CHECKLIST (REF. TO CERTIFICATES)**

S.No.	Component	Remark	Observation	Remarks
1.	Powder Hopper	MOC Certificate		
2.	Stirrer	MOC Certificate		
3.	Powder outlet pipe	MOC Certificate		
4.	Powder drum	MOC Certificate		
5.	Scraper block	MOC Certificate		
6.	Scraper 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		

**9.0 VERIFICATION OF TEST CERTIFICATES**

S.No.	Component	Type of Certificate	Observation	Remarks
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		



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**10.0 POWER AND UTILITY CHECKLIST**

S.No.	Utility Parameter	Method of verification	Acceptance Criteria	Observation	Remarks
1.	Phase	Visual Check	3 Phase		
2.	Voltage				
	Test (Using Multimeter)	R ∇ Y Y ∇ B R ∇ B	415 ± 10% 415 ± 10% 415 ± 10%		
3.	Frequency	Multimeter	50 Hz		

**11.0 ATTACHMENT LOG**

S.No.	Documents	Observation	Remarks
1.			
2.			
3.			
4.			
5.			



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**12.0 PARTICIPANT LOG**

All persons involved in execution of this protocol must sign below.

Name	Designation	Department	Signature with Date

**13.0 VARIATIONS**

Should there be any addition / modification in the IQ or the equipment after its Installation, then, the same shall be duly incorporated on mutual agreement of the Customer and the Manufacturer, in writing, after verifying the technical feasibility of the same subjected to cost implications, if any.





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**15.0 ABBREVIATIONS**

S.No.	Abbreviations	Expanded Definition
1.	PLC	Programmable Logic Controller
2.	HMI	Human Machine Interface
3.	MOC	Material of Construction
4.	SS	Stainless Steel
5.	MCB	Miniature Circuit Breaker
6.	SMPS	Switch Mode Power Supply
7.	FR	Filter Regulator
8.	mm	Millimeter
9.	Hg	Mercury
10.	LPM	Litre per minute
11.	CFM	Cubic Feet per Minute
12.	V	Volt
13.	A	Ampere
14.	Hz.	Hertz
15.	DC	Direct Current
16.	HP	Horsepower
17.	RPM	Revolutions per Minute





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**16.0 APPROVAL SHEET FROM .....**

<b>Department</b>	<b>Name</b>	<b>Designation</b>	<b>Sign</b>	<b>Date</b>