



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

PROTOCOL No.:

TABLE OF CONTENTS

S.No.	Content	Page No.
1.0	System Information	2
2.0	Objective	3
3.0	Scope	3
4.0	Responsibility	3
5.0	Equipment Description	4
6.0	Technical Specification	7
7.0	Product Contact Surface Area	9
8.0	Material of Construction of various parts	9
9.0	PLC and HMI Specifications	10
10.0	HMI screen details – Technical write-up	10
11.0	Power and Utility consumptions	11
12.0	List of Bought-out items	12
13.0	List of Test Certificates	14
14.0	Safety features and Interlocks	15
15.0	Limiting conditions for machine performance	16
16.0	List of supporting documents	16
17.0	Variations	16
18.0	Review and comments	17
19.0	Abbreviations	18
20.0	Approval sheet from the Customer	19



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

PROTOCOL No.:

1.0 SYSTEM INFORMATION

Manufacturer	Regd. Office	Works
Customer		
Site		

Protocol Prepared & Released By

Name of the Manufacturer	Signing Authority & Designation	Signature	Date

Protocol Approved By

Name of the Customer	Signing Authority & Designation	Signature	Date

 <p>PHARMA DEVILS</p>	<p>DESIGN QUALIFICATION FOR AUTOMATIC CAPSULE FILLING MACHINE WITH POWDER, PELLET AND TABLET FILLING ATTACHMENT</p>	<p>PROTOCOL No.:</p>
--	--	-----------------------------

2.0 OBJECTIVE

- 2.1 The Design Qualification Protocol (hereafter referred to as ‘DQ’) shall specify the Design Parameters of the Automatic Capsule Filling Machine With Powder, Pellet And Tablet Filling Attachment (Hereafter referred to as ‘A120’) being manufactured byfor M/s.
- 2.2 This protocol shall confirm that the machine being manufactured shall comply with the specifications laid down in this protocol.

3.0 SCOPE

- 3.1 The scope of this DQ shall be confined to Pharmafill A120.
- 3.2 The Qualification of any additional accessories apart from those specified in this DQ 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 DQ.
- 3.4 The equipment shall be intended for filling Powder, Pellets and Tablets into the hard gelatin capsules.
- 3.5 The equipment shall operate in a dust-free environment with humidity in the range 45–55% RH and temperature in the range of 20 – 25 deg C.

4.0 RESPONSIBILITIES

4.1 Manufacturer

- 4.1.1 To provide the complete technical details of the equipment pertaining to its operational functions.
- 4.1.2 To prepare the DQ incorporating the following major parameters:
 - Equipment Description
 - Technical Specifications
 - PLC and HMI specifications
 - Technical write-up of the HMI screen details
 - Material of Construction of different parts
 - Utility Consumption

4.2 Customer

- 4.2.1 To verify the DQ.
- 4.2.2 To approve the DQ.

5.0 EQUIPMENT DESCRIPTION

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

5.1 Production Zone

- 5.1.1 The production zone encompasses the upper portion of the Capsule Filling Machine and is enclosed by the acrylic doors followed by interlock system.



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

PROTOCOL No.:

- 5.1.2 The production zone includes the loader assembly, powder assembly with rejection system, unseparated capsule rejection assembly, locking assembly, ejection assembly and turret assembly.
- 5.1.3 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.
- 5.1.4 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.
- 5.1.5 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.
- 5.1.6 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.
- 5.1.7 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.
- 5.1.8 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 1)
- 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



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

PROTOCOL No.:

- Station for idle station
- Station for ejecting the capsule
- Station for cleaning the segments

5.2 Non-Production Zone

- 5.2.1 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
- 5.2.2 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.
- 5.2.3 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.
- 5.2.4 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.
- 5.2.5 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
- 5.2.6 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.

5.3 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

5.4 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



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

PROTOCOL No.:

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.

5.5 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.

6.0 TECHNICAL SPECIFICATION

S.No.	Parameter	Specification
1.	Capacity / Output	1,00,000 to 1,20,000 capsules / hr for powder Depending up on the quality of capsules, characteristics of Powder to be filled, Fill weight & the room condition. 80,000 to 1,00,000 capsules / hr for pellet Depending up on the quality of capsules, characteristics of Pellet to be filled, Fill weight & the room condition. 60,000 to 70,000 capsules / hr for Tablet Depending up on the characteristics of tablet to be filled i.e. shape, quality, Dimensions & the room condition.
2.	Capsule size	Machine is suitable for Any size from '00 to 4; however Size#0 and Size#3 will be supplied as ordered.
3.	Product to be filled	Powder, Pellet & Tablet
4.	No. of holes on the segment	18
5.	No of station on turret	12
6.	Surface Finish	Internal Product Contact Parts - Mirror Finish External Zone - Matt Finish
7.	Mode of machine cleaning	During the running of the machines, the segments are cleaned by means of vacuum and positive compress air flow at the 12 th station. The general cleaning of the machine is to done manually.
8.	Filled weight accuracy	± 5% (depending on Powder/pellet characteristics)
9.	Room temperature	NLT 20 deg C and NMT 25 deg C
10.	Room humidity	NLT 45 %RH and NMT 55 %RH
11.	Main motor HP	2 HP, 1410 RPM, 415V, 50HZ
12.	Vacuum pump motor HP (2 No.)	3 HP, 1410 RPM, 415V, 50HZ
13.	Vacuum pump (2 No.)	26" Hg, 1000 LPM



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

PROTOCOL No.:

S.No.	Parameter	Specification
14.	Blower motor HP	5 HP, 2900 RPM, 415 V, 50HZ
15.	Blower	265 mm, 340 m3/hr
16.	Capacity of the Capsule Hopper in Ltr	32 Ltr
17.	Capacity of the powder Hopper in Ltr	32 Ltr
18.	Capacity of the pellet Hopper in Ltr	12 Ltr
19.	Capacity of the Tablet Hopper in Ltr	7 Ltr
20.	<u>Packing Specifications</u>	
	Machine Dimensions (in mm) - Approx.	AS per GA Drawing

7.0 PRODUCT SURFACE CONTACT AREAS

S.No.	Component	Surface Area (in sq. cm)
1.	Capsule Hopper	43373.6
2.	Powder Hopper	264449.5
3.	Magazine	56750.56
4.	Raceway	41099.73
5.	Pusher Block	962.3
6.	Releasing Finger Block	381.64
7.	Top Segment	1137.01
8.	Bottom Segment	2273.56
9.	Scraper Block	9785.05
10.	Dosing Disc	12787.065
11.	Pellet Hopper	3173.85
12.	Pellet Discharge Pipe	407.88

8.0 MATERIAL OF CONSTRUCTION OF VARIOUS PARTS

S.No.	Component	Remark
1.	Powder Hopper	SS 316
2.	Stirrer	SS 316
3.	Powder outlet pipe	SS 316
4.	Powder drum	SS 316
5.	Scraper block	SS 316
6.	Scraper holding plate	SS 316
7.	Dosing disc	SS 316
8.	Tamping punch	SS 316
9.	Top segment	SS 316
10.	Bottom segment	SS 316
11.	Pellet Hopper	SS 316
12.	Pellet Discharge Pipe	SS 316



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

PROTOCOL No.:

9.0 PLC AND HMI SPECIFICATIONS:

S.No.	Parameter	Specification
PLC Details		
1.	Make	Mitsubishi
2.	Model	FX3GE 40 M
HMI Details		
1.	Make	Beijer
2.	Model	X2 Base 10

10.0 HMI SCREEN DETAILS – TECHNICAL WRITE-UP

- Power on screen – This screen indicates the various modes of operation. It enables to navigate to different screens.
- Manual function screen – This screen facilitates in operating the machine in manual mode.
- Auto function & Parameter screen – This screen facilitates in operating the machine in auto mode and also to select the sampling process.
- Recipe Screen – This screen enables to generate Recipe by feeding the parameters required for the Functioning of the machine.
- Input Screen – This screen enables to know the status of the inputs on the PLC.
- Output Screen – This screen enables to know the status of the outputs on the PLC.
- Interlock Screen – This screen enables to know the status of the Interlocks on the PLC.
- Alarm screen – This screen enables to know the status of the alarm.

11.0 POWER AND UTILITY CONSUMPTION

Power Consumption:

S.No.	Parameter	Specification
1.	Voltage	415 V \pm 10%
2.	Frequency	50 Hz \pm 5%
3.	Connected Load	13.5 HP

Major Cabling details (In Client scope)

S.No.	Parameter	Specification
1.	For Main supply	6 Sq.mm x 6 Core (Cu Armoured)
2.	For Vacuum Pump motor	2.5 Sq.mm x 4 Core
3.	For De Dusting Blower motor	2.5 Sq.mm x 4 Core



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

PROTOCOL No.:

Utility Consumption:

S.No.	Parameter	Specification
1.	Compressed Air	NLT 6 kg/sq.cm, Moisture free

12.0 LIST OF BOUGHT-OUT ITEMS

Mechanical

S.No.	Component	Manufacturer
1.	Main gearbox	Bonfiglioli/ equivalent
2.	Powder feeder gearbox	Bonfiglioli/ equivalent
3.	De-dusting blower	Minivac / equivalent
4.	Vacuum Pump	Minivac / Equivalent
5.	Vacuum & de-dusting tank filter bag	Material – PC Satin

Electrical

S.No.	Component	Manufacturer
1.	Main motor	Bonfiglioli/ equivalent
2.	Powder feeder motor	Bonfiglioli/ equivalent
3.	De-dusting blower motor	Hindustan / equivalent
4.	Vacuum pump motor	Hindustan / Equivalent
5.	MCB	Schneider / equivalent
6.	Variable Frequency Drive	Mitsubishi / equivalent
7.	Contactors	Siemens / equivalent
8.	Overload relays	Siemens / equivalent
9.	PLC	Mitsubishi / equivalent
10.	Add on cards	Mitsubishi / equivalent
11.	HMI	Beijer / equivalent
12.	SMPS	Omron / equivalent
13.	Relay Card	Shavison Electronics / equivalent
14.	Brake Relay	Siemens / Equivalent
15.	Single Phase Preventer	GIC / Equivalent
16.	Capsule level Sensors	SICK Controls / equivalent
17.	Pellet level Sensor	SICK Controls / equivalent



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

PROTOCOL No.:

S.No.	Component	Manufacturer
18.	Powder Sensor	IFM controls/ equivalent
19.	Tablet Sensor	Panasonic / equivalent
20.	Door Sensor	SICK Controls / equivalent

Pneumatic

S.No.	Component	Manufacturer
1.	Pressure switch for Main air pressure	Panasonic / Equivalent
2.	Pressure switch for vacuum	SMC Pneumatics / Equivalent
3.	Solenoid valves	SMC Pneumatics / Equivalent
4.	Actuating Cylinder for loader	CKD / Equivalent
5.	Actuating Cylinder for sampling	SMC / Equivalent
6.	Pneumatic actuator for tablet attachment	Festo / Equivalent
7.	FRL Unit	Festo / SMC Pneumatics / Equivalent
8.	Tubing	Festo / SMC Pneumatics / Equivalent
9.	Connectors	Festo / Equivalent
10.	Solenoid Coils	Festo / SMC Pneumatics / Equivalent
11.	Silencers	Festo / SMC Pneumatics / Equivalent
12.	Manifold	SMC Pneumatics / Festo / Equivalent

13.0 LIST OF CERTIFICATES

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



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

PROTOCOL No.:

14.0 SAFETY FEATURES AND INTERLOCKS:

S.No.	Safety feature	Specified function
1.	Main ON / OFF switch	To isolate the control panel from the input supply.
2.	Password protection at operator interface	To assign specific controls to the operator, supervisor and Manager.
3.	Hardware Emergency switch at Operator Console	For Operator Safety.
4.	Main Motor VFD fault	For Motor & equipment protection.
5.	Vacuum Pump Overload	For Motor & equipment protection.
6.	Blower Motor Overload	For Motor & equipment protection.
7.	Stirrer Motor Overload	For Motor & equipment protection.
8.	Vacuum pressure drop interlock	For safety of the batch
9.	Air pressure drop interlock	For safety of the batch & the process.
10.	Capsule level low – Machine stop	For safety of the batch & the process.
11.	Powder level low – Machine stop	For safety of the batch & the process.
12.	Pellet level low – Machine stop	For safety of the batch & the process.
13.	Consecutive Tablet Unfilled – Machine stop	For safety of the batch & the process.
14.	Door interlock	For Operator safety.

15.0 LIMITING CONDITION FOR MACHINE PERFORMANCE

15.1 Power Failure

In the event of power failure, the process shall halt, but the PLC through a battery back up facility will save the data recorded for retrieval.

15.2 Control Panel Failure

Failure in the control panel shall result in the stoppage of process. However, data, till the stoppage occurred, will get saved in the memory of the PLC system. Suitable alarms will be provided in the operator interface.

15.3 Compressed Air Failure

Failure or drop in pressure of the compressed air supply will result in the stoppage of the process. However, data till the stoppage occurred will get saved in the memory of the PLC system. The System will start at the same point once the compressed air is restored.

16.0 LIST OF SUPPORTING DOCUMENTS:

S.No.	Documents
1.	G.A. Drawing



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

PROTOCOL No.:

19.0 ABBREVIATIONS:

S.No.	Abbreviations	Expanded Definition
1.	kg	Kilogram
2.	SS	Stainless Steel
3.	SWG	Standard Wire Gauge
4.	NLT	Not Less Than
5.	NMT	Not More Than
6.	Hg	Mercury
7.	Sq. mm.	Square Millimeter
8.	L	Length
9.	W	Width
10.	H	Height
11.	mm	Millimeter
12.	MOC	Material of Construction
13.	V	Volt
14.	A	Ampere
15.	Hz.	Hertz
16.	kW	Kilowatt
17.	Cu	Copper
18.	kg/hr.	Kilogram per hour
19.	NL	Non-Lubricating
20.	MCB	Miniature Circuit Breaker
21.	HP	Horsepower
22.	RPM	Revolutions per Minute
23.	G.A.	General Assembly
24.	kb	Kilobyte



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

PROTOCOL No.:

20.0 APPROVAL SHEET FROM.....

Department	Name	Designation	Sign	Date