



**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
AUTOMATIC CAPSULE FILLING MACHINE**

**PROTOCOL No.:**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
AUTOMATIC CAPSULE FILLING  
MACHINE**

<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES PROTOCOL No.</b>	<b>NIL</b>



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**1.0 PRE – APPROVAL:**

**PREPARED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>OPERATING MANAGER (QUALITY ASSURANCE)</b>			
<b>HEAD (PRODUCTION)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>HEAD (QUALITY ASSURANCE)</b>			



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**2.0 OBJECTIVE:**

- To prepare the Design Qualification on the basis of URS, Purchase Order and information given by Supplier.
- The purpose of Design qualification is to ensure that all Critical Aspects of Process/Product Requirement, GMP and Safety have been considered in designing the equipment and is properly documented.

**3.0 SCOPE:**

- The Scope of this Qualification Document is limited to the Design Qualification for Automatic Capsule Filling Machine with GMP Model procured from ..... for .....
- The equipment shall operate under the dust free environment and conditions as per the GMP requirements.
- The drawings and P & ID's provided by Vendor shall be verified during Design Qualification.



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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
<b>Quality Assurance</b>	<ul style="list-style-type: none"> <li>• Initiation, Authorization and Approval of the Protocol cum Report.</li> <li>• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.</li> <li>• Review of Qualification Protocol cum Report after Execution.</li> <li>• Co-ordination with Production and Engineering to carryout Design Qualification.</li> <li>• Monitoring of Design Qualification Activity.</li> </ul>
<b>Production</b>	<ul style="list-style-type: none"> <li>• Review of the Protocol cum Report.</li> <li>• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.</li> <li>• Post Approval of Qualification Protocol cum Report after Execution.</li> </ul>
<b>Engineering</b>	<ul style="list-style-type: none"> <li>• Review of the Protocol cum Report.</li> <li>• Assist in the Preparation of the Protocol cum Report.</li> <li>• To co-ordinate and support the Activity.</li> <li>• To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e.               <ul style="list-style-type: none"> <li>➤ GA Drawing.</li> <li>➤ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/brochures.</li> <li>➤ Details of utilities Required.</li> <li>➤ Identification of components for calibration.</li> <li>➤ Material of construction of Product Contact Parts.</li> <li>➤ Brief Process Description.</li> <li>➤ Safety Features and Alarms.</li> </ul> </li> <li>• Review of Qualification Protocol after Execution.</li> </ul>



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**5.0 BRIEF PROCESS DESCRIPTION:**

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

**5.1 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, un-separated 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 6<sup>th</sup> 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 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



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- 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

## **5.2 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.


## **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 pneumatic cylinder arrangement. Tablet filling attachments for capsule size #0 will be fits either side of the powder filling station.

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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 EQUIPMENT SPECIFICATION:**

Equipment Specifications are based on User Requirement Specification prepared by..... The manufacturer of equipment ensures complies with User Requirement Specification. This is Automatic capsule filling machine.

**7.0 CRITICAL VARIABLES TO BE MET:**

**7.1 PROCESS/PRODUCT PARAMETERS:**

Parameters	Acceptance Criteria	Reference
<b>Model</b>	The equipment should be a GMP compliant model.	Design Requirement
<b>Material of Construction</b>	All contact part should be made up of SS 316L. Other non-contact component are of SS304	Design Requirement
<b>Process</b>	Equipment should be able to compress the blended material into tablets.	Design Requirement
<b>Cleaning &amp; Maintenance</b>	Should be easily cleanable and maintainable	Design Requirement
<b>Safety</b>	Adequate safety features for men & material to be provided along with the equipment	Design Requirement
<b>Control System</b>	Equipment to be controlled by PLC & Manual	Design Requirement
<b>Electrical System</b>	The electrical system of the equipment to be housed as per the GMP & GEP slandered	Design Requirement





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**7.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:**

Critical Variables	Acceptance Criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
<b>Electrical Supply</b>	3 Phase Plus Earthing, 5 Wire Line Up To The Panel Board Terminal. Voltage- 415 V Frequency- 50 Hz, 3 Phase, AC (To be assured by Engineering Department)	GMP Requirement
<b>Electrical Connections on Machine/Panel</b>	415V, 3 Phase, 50 Hz,	
<b>Room Condition</b>	Should be able to meet the requirement of clean environment.	

**7.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:**

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 <sup>th</sup> station. The general cleaning of the machine is to done manually.



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S.No.	Parameter	Specification
8.	Filled weight accuracy	± 5% (depending on Powder/pellet characteristics)
9.	Room temperature	NLT 20 °C and NMT 25 °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
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.	<b>Packing Specifications</b>	
	Machine Dimensions (in mm) - Approx.	As per GA Drawing

**7.4 MATERIAL OF CONSTRUCTION:**

S.No.	Parts Name	Material of Construction
<b>MOC of Contact parts</b>		
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



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**7.5 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.	Scrapper Block	9785.05
10.	Dosing Disc	12787.065
11.	Pellet Hopper	3173.85
12.	Pellet Discharge Pipe	407.88

**7.6 MAJOR BOF COMPONENT DETAIL:**

S.No.	PARTICULARS	SPECIFICATIONS
<b>MECHANICAL</b>		
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
<b>ELECTRICAL</b>		
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



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S.No.	PARTICULARS	SPECIFICATIONS
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
18.	Powder Sensor	IFM controls/ equivalent
19.	Tablet Sensor	Panasonic / equivalent
20.	Door Sensor	SICK Controls / equivalent
<b>PNEUMATIC</b>		
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
<b>PLC Details</b>		
01	Make	Mitsubishi
02	Model	FX3GE 40 M
<b>HMI Details</b>		
01	Make	Beijer
02	Model	X2 Base 10



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**7.6.1 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 facilitate 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.

**7.7 SAFETY FEATURES & ALARMS:**

S.No.	Alarm	Description
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.



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**7.8 LIMITING CONDITION FOR MACHINE PERFORMANCE:**

**7.8.1 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.

**7.8.2 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.

**7.8.3 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.

**7.9 POWER AND UTILITY CONSUMPTION:**

S.No.	PARTICULARS	SPECIFICATIONS
<b>Power Consumption</b>		
1.	Voltage	415 V $\pm$ 10%
2.	Frequency	50 Hz $\pm$ 5%
3.	Connected Load	13.5 HP
<b>Major Cabling details (In Client scope)</b>		
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
<b>Utility Consumption</b>		
1.	Compressed Air	NLT 6 kg/sq.cm, Moisture free



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**7.10 VENDOR SELECTION:**

<b>Critical Variables</b>	<b>Acceptance Criteria</b>	<b>Reference</b>
Selections of Vendor for supplying the Automatic capsule filling Machine.	Selection of Vendor is done on the basis of review of vendor. Criteria for review is include vendor background (general/ financial), technical knowhow, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

**Reference:** (1) The equipment shall confirm to the specifications and requirement as specified in PO.  
(2) Operating and service manual for Automatic capsule filling Machine.

**Reviewed By**  
**Sign & Date**







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**12.0 ABBREVIATIONS:**

PVT.	:	Private limited
LTD.	:	Limited
DQ.	:	Design 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
%	:	Percentage
LPM	:	Liter per minutes
Kg.	:	Kilo gram
GMP	:	Good Manufacturing Practice
P.O.	:	Purchase Order
Hz	:	Hertz
H.P.	:	Horse Power
A.C.	:	Alternating Current
V	:	Voltage
RPM	:	Rotation per Minute
mm	:	Millimeter
S.S.	:	Stainless Steel
MOC	:	Material of Construction
GA	:	General Arrangement
P & ID	:	Piping and Instrumentation Diagram
M. S.	:	Mild Steel
PLC	:	Programmable logical controller



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**13.0 REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (ENGINEERING)</b>			

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (PRODUCTION)</b>			

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (QUALITY ASSURANCE)</b>			