1.0 PROTOCOL APPROVAL:

Signing of this approval page of Protocol indicates agreement with the qualification approach described in this document. If modification to the qualification approach becomes necessary, an addendum shall be prepared and approved .The protocol cannot be used for execution unless approved by the following authorities.

This Installation Qualification protocol of Automatic capsule filling machine has been reviewed and approved by the following persons:

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
PREPARED BY			QUALITY ASSURANCE		
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		

2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of developing and executing this protocol is to collect sufficient data pertaining to the Automatic capsule filling machine and define the qualification requirements and acceptance criteria for the Automatic capsule filling machine. Successful completion of these qualification requirements will provide assurance that the Automatic capsule filling machine was installed as required in the production area.

The objective of the installation qualification is to prove that each activity proceeds as per design specification and the tolerances prescribed there in the document and is the same at utmost transparency.

2.2 PURPOSE:

The purpose of this protocol is to establish documentary evidence to ensure that the Automatic capsule filling machine system received matches the Design specification and also to ensure that it is properly and safely installed.

Purpose of Automatic capsule filling machine shall be used for capsule filling different capsule size to be used in the formulation. The equipment shall operate under dust free environment and conditions as per the GMP requirements.

2.3 SCOPE:

This Protocol is applicable to installation of Automatic capsule filling machine at the tablet manufacturing facility in …….. & the subsequent documentation.

2.4 RESPONSIBILITY:

In accordance with protocol, following functions shall be responsible for the qualification of system.

Execution Team (Comprising members from Production, Engineering and Quality Assurance) and their responsibilities are following:

- Prepares the qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures on system Qualification.
- Distributes the finalized protocol for review and approval signatures.
- Execution of Qualification protocol.
- Review of protocol, the completed qualification data package, and the final report.
- The installation checks, operational checks, calibration, SOP identification, identification features, identification of utility supply shall be carried out by engineering persons
- The production operator/supervisor shall carry out the cleaning and operation of machine.

Head – Production/Engineering:

- Review of protocol, the completed qualification data package, and the final report.
- Assist in the resolution of validation deficiencies.

Head – Operation and Quality Assurance:

- Review and approval of protocol, the completed qualification data package, and the final report.

2.5 EXECUTION TEAM:

The satisfactory installation of the Automatic capsule filling machine shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the Automatic capsule filling machine installed and is satisfactorily integrated.

Execution team is responsible for the execution of installation of Automatic capsule filling machine. Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 ACCETANCE CRITERIA:

3.1 The Automatic Capsule Filling Machine shall meet the system description given in design qualification.

3.2 The Automatic Capsule Filling Machine shall meet with the acceptance criteria mentioned under the topic “Identification of major components”

3.3 The Automatic Capsule Filling Machine system shall be operated by manual /PLC.

4.0 REVALIDATION CRITERIA:

The Automatic Capsule Filling Machine has to be revalidated if

- There are any major changes in system components which affect the performance of the system
- After major breakdown maintenance is carried out.
- As per revalidation date and schedule

5.0 INSTALLATION QUALIFICATION PROCEDURE:

5.1 AUTOMATIC CAPSULE FILLING MACHINE SYSTEM DESCRIPTION

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

Production Zone

- The production zone encompasses the upper portion of the Capsule Filling Machine and is enclosed by the acrylic doors.
- The production zone includes the loader assembly, powder assembly, rejection assembly, locking assembly, ejection assembly, turret assembly and additional 3 Nos. attachments for tablet filling attachment.
- 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 indexer. 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.

- 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
  - Upward movement of the top segment and backward movement of the bottom segment
  - First station for filling of Tablet into the capsule
  - Second station for filling of Tablet into the capsule
  - Station for filling powder into the capsule
  - Third station for filling Tablets into the capsule
  - Station for rejecting the un-separated capsules
  - Idle station.
  - Downward movement of the top segment and forward movement of the bottom segment
  - Station for locking the capsule
  - Station for ejecting the capsule
  - Station for cleaning the segments

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 indexer 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 also placed in the non production zone. 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.
- The drive to the tablet filling attachment for respective 3 stations is through separate chain & sprockets arrangement on the main shaft.

Tablet filling attachment

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 cam lever mechanism

Control System

The Control system for the equipment is a standard controls 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.

5.2 INSTRUCTION FOR FILLING THE CHECKLIST

5.2.1 Write down the actual observation in the observation column

5.2.2 Give the detailed information in the summary and conclusion part of the Installation Qualification report.

5.2.3 Whichever column is blank or not used ‘NA’ shall be used.

5.3 INSTALLATION CHECKLIST:

Installation checklist is as follows:

S.No.	Statement	Observation	Method of verification	Checked by (Sign/Date)
1.	Verify that the “As Built” drawing is complete and represents the design concept.			
2.	Verify that major components are securely anchored and shock proof.			
3.	Verify that there is no observable physical damage.			
4.	Verify that there is sufficient room provided for servicing.			
5.	Verify that all piping and electrical connections are done according to the drawings.			
6.	All access ports are examined and cleared of any debris.			
7.	Safe electrical connections.			
8.	Wiring diagram affixed to inside section of control panel.			
9.	Equipment identification nameplate visible.			
10.	Units installed on foundation are secure in place as per manufacturer’s recommendations.			

Remark: ----------

Reviewed by (Sign/Date)

5.4 IDENTIFICATION OF MAJOR COMPONENTS:

Describe each critical component and check them and fill the inspection checklist.

S.No.	Component Description	Specification	Observation	Checked By/Date
Mechanical				
1.	Main motor	Make- Bonfiglioli, BN90LA4, 1390 RPM2 HP, 415 V, 50 Hz		
2.	Main gearbox	Bonfiglioli make, AS25 P P90/B3/11-51		
3.	Powder feeder motor	Bonfiglioli Make, BN63B4, 0.25 HP, 415 V, 50 Hz		
4.	Powder feeder gearbox	Bonfiglioli make, VF44 F1 P63 B5/B2/28		
5.	De-dusting blower	Minivac make, Model – SVRD 150, Vacuum -135 mm Hg, 235 CFM		
6.	De-dusting blower motor	Hindustan Motor Make, 3 HP, 2800 RPM, 415 V, 50 Hz		
7.	Vacuum Pump	Indovac Make, Model IVS-1000, 26” Hg Vacuum, 1000 LPM		
8.	Vacuum pump motor	Hindustan Motor make, 3 HP, 1400 RPM, 415 V, 50 Hz		
9.	Vacuum & de-dusting tank filter bag	Material – PC Satin		
Electrical				
10.	MCB for Main Motor	Make – Schneider, 10A, 2 pole		
11.	MCB for control circuit,	Make – Schneider, 4 A, 2 pole		

	PLC, SMPS			
12.	MCB for Vacuum Blower & Accessories	Make – Schneider, 32 A, 3 pole		
13.	Contactor for vacuum pump	Make – Siemens, 3TF30, 9 A		
14.	Contactor for de-dusting blower	Make – Siemens, 3TF30, 9 A		
15.	Contactor for powder feeder motor	Make – Siemens, 3TF30, 9 A		
16.	Overload relay for vacuum pump	Make – Siemens, 3UA50 3.2-5 A		
17.	Overload relay for de-dusting blower	Make – Siemens, 3UA50 3.2-5 A		
18.	Overload relay for powder feeder motor	Make – Siemens, 3UA50 0.6-1 A		
19.	Relay Cards	Make – Shavison Electronics, 8 Way, 24 V DC		
20.	SMPS	Make – Shavison Electronics, Model: G31-60-24 Output – 24 V,2.5 A		
21.	PLC	Make – Mitsubishi, FX1N-40MT		
22.	PLC Add on Input card	Make – Mitsubishi, FX2N-16 EX		
23.	PLC analog card	Make – Mitsubishi, FX1N-1DABD		

24.	HMI	Make – Mitsubishi, E1061		
25.	VFD	Make – Mitsubishi FRD 740-036-EC		
26.	Emergency P/B	Make – Teknic		
27.	Inductive sensor – Machine Speed	Make –ACCENT 10-30 VDC, 8 mm PNP, Max load 300 mA		
28.	Inductive sensor – Capsule level	Make –ACCENT 10-30 VDC, 8 mm PNP, Max load 300 mA		
29.	Capacitive sensor – Powder Level	Make –ACCENT 10-30 VDC, 10mm PNP, Max load 300 mA		
30.	Tablet sensor	Make- Wenglor Model ODX402P0088 Supply Voltage- 18-30 VDC Response time - 250µs		
Pneumatic				
31.	Pressure switch for Main air pressure	Make – Indfos, Model: IPS100		
32.	Digital pressure switch for vacuum.	Make – SMC, Model: ZSE 30		
33.	Actuating Cylinder	Make – FESTO, Model: DSN-16-25-P 16 mm bore x 25 mm		

		stroke		
34.	FR Unit	Make – Festo, Model: LFR– D –Mini, ¼" BSP Filter Regulator		
35.	Solenoid Valves	Make – SMC Pneumatics I-SY-5120-4-LZ		
36.	Manifold	Make – SMC Pneumatics, i-SS5Y5-20-03-RSX 105813		
37.	Silencers	Make – SMC Pneumatics, AN203-02		
38.	Solenoid Coils	Make – SMC Pneumatics,		
39.	Tubings	Make – SMC Pneumatics, PU6 & PU8		

Remark: ----------

Reviewed by (Sign/Date)

5.5	IDENTIFICATION OF SUPPORTING UTILITIES:		
UTILITY	**PROPERLY IDENTIFIED & CONNECTED**	**OBSERVATION**	**CHECKED BY (SIGN/DATE)**
1) Electricity:	3 Phase 440 Volts, 50Hz		
2) Compressed air:	NLT 5kg/cm^2		

Remark: ----------

Reviewed by (Sign/Date)

5.6 IDENTIFICATION OF SAFETY FEATURES:

Identify and record the safety features (if any) and their function in following tables:

SAFETY FEATURES DESCRIPTION	FUNCTION	OBSERVATION	CHECKED BY (SIGN/DATE)
Hardware Emergency switch at Operator Console	For Operator Safety.		
Vacuum pressure drop interlock	For safety of the batch	.	
Door interlock	For Operator safety.		
Password protection at operator interface	To assign specific controls to the operator, supervisor and Manager.		
Air pressure drop interlock	For safety of the batch & the process.		

Remark: ----------

Reviewed by (Sign/Date)

5.7 IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP)

The following Standard Operating Procedures were identified as important for effective performance of Automatic capsule filling machine.

S. No.	SOP Title	Verified By Sign/ Date

Remark: ----------

Reviewed by (Sign/Date)

5.8 IDENTIFICATION OF COMPONENT TO BE CALIBRATED

In the Automatic Capsule Filling Machine following are the components, which needs calibration. They shall be calibrated during/ before installation of the equipment at the site:

Name of Components	Range	Make	ID	Location	Identified By Sign/Date

Remark: ----------

Reviewed by (Sign/Date)

5.9 MATERIAL OF CONSTRUCTION VERIFICATION

S.No.	Component	MOC	Observation	Method of verification	Checked by (Sign/Date)
1.	Powder hopper	SS316			
2.	Punch	SS316			
3.	Top Segment	SS316			
4.	Bottom Segment	SS316			
5.	Dosing disc	SS316			
6.	Drum	SS316			

Remark: ----------

Reviewed by (Sign/Date)

5.10 VERIFICATION OF DRAWING AND DOCUMENTS:

Following documents are reviewed and attached as listed below:

S.No.	DRAWING AND DOCUMENT DETAIL	VERIFIED BY (Sign/Date)

Remark: ----------

Reviewed by (Sign/Date)

5.11 ABBREVIATIONS

Following Abbreviations are used in the installation qualification protocol of Capsule Filling machine

MOC: Material Of Construction

BHP: Break Horse Power

HMI/MMI: Human/Man Machine Interface

FAT: Factory Acceptance Test

CFM: Cubic Feet Per Minute

GEP: Good Engineering Practices

FLP: Flame Proof

MS: Mild Steel

PLC: Programmable Logic Controller

SS: Stainless Steel

MCB: Miniature Circuit Breaker

SMPS: Switch Mode Power Supply

RPM: Revolution Per Minute

LPM: Liter Per Minute

FR: Filter Regulator

HP: Horsepower

5.12 DEFICIENCY AND CORRECTIVE ACTION (S) REPORT (S)

Following deficiency was identified and corrective actions taken in consultation with the validation team.

Description of deficiency:

Corrective action(s) taken:

Deviation accepted by
(Sign/Date)

Deviation Approved by:
(Sign/Date)

5.13 Annexure(s):

Sr. No.	Annexure No.	Title of Annexure

Remarks (if any)**:**

_____

_____

Done By & Date: **Verified By & Date:**

6.0 INSTALLATION QUALIFICATION FINAL REPORT:

All the IQ data sheets and discrepancy report shall be reviewed by validation team to prepare summary report. The summary of IQ shall be used to draw conclusion for approval of installation qualification report.

6.1 SUMMARY :

6.2 CONCLUSION :

Prepared By
Sign/Date

Checked By
Sign/ Date

6.3 FINAL REPORT APPROVAL

It has been verified that all tests required by this protocol are completed, reconciled and attached to this protocol or included in the qualification summary report. Verified that all amendments and discrepancies are documented, approved and attached to this protocol.

Signature in the block below indicate that all items in this qualification report of Automatic capsule filling machine have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		