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.

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 machine and to prove that each operation proceeds as per design specification and the tolerances prescribed there in the document, are 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 received matches the Design specification and also to ensure that it is properly and safely installed.

2.3 SCOPE:

The Scope of this protocol is limited to the Operational Qualification of Automatic capsule filling machine in ……..

Once the operational qualification of Automatic capsule filling machine has been completed successfully, the equipment shall be proceeded for the performance qualification procedure.

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 operational checks, calibration, SOP verification, verification of safety features, verification of utility supply shall be carried out by engineering persons and production person.
- 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 operation 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 is operational and is satisfactorily working.

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 It shall be complying with all the designed specifications.

3.2 All supporting utilities of specified capacities shall be placed near the equipment.

4.0 REVALIDATION CRITERIA:

The machine shall be revalidated if

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

5.0 OPERATIONAL QUALIFICATION PROCEDURE

5.1 EQUIPMENT DESCRIPTION:

Equipment Name	:	Automatic capsule filling machine
Supplier/Manufacturer	:	Anchor Mark Pvt. Ltd.
Machine Dimensions (in mm) – Approx (L x W x H)	:	1285 x1100 x 1870 3000 x 2700 x 2200 (Acrylic doors in open condition.)
Working Capacity	:	25000/Hrs.
Model	:	Pharmafill A60
Serial no.	:	1106017
Location	:	Capsule filling Area

Automatic capsule filling machine comprises of following components.

1. Structure Assembly
2. Main Drive assembly
3. Turret Assembly

4. Loader Assembly
5. Powder Assembly.
6. Hopper Assembly
7. PLC

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 Operational Qualification report.

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

5.3 TEST INSTRUMENT DETAILS

This test is intended to describe the equipments/instruments and its complete details to have a traceability to the national standard which is to be used for the verification of the operation of the Automatic capsule filling machine.

S.No.	Name of Instrument	Inst. ID. Number	Calibration done on	Calibration Due date	Certificate Number

Checked by Date:

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

Reviewed by (Sign/Date)

5.4 Verification of Calibrated component :

This test is intended to describe the equipments/instruments and its complete details to have a traceability to the national standard, which is to be used for the verification of the operation of the Automatic capsule filling machine.

S.No.	Name of Instrument	Inst. ID. Number	Calibration done on	Calibration valid up to	Certificate number

Checked by Date:

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

Reviewed by (Sign/Date)

5.5 VERIFICATION OF FUCTIONAL CHECKS:

Name of system component	Specified function	Observation	Method of verification	Verified by (Sign/date)
1. Turret Assembly				
Turret	To drive the twelve station indexer			
Station 1	To load and separate of capsule			
Station 2	For movement of top segment and backward movement of bottom segment			
Station 3	To fill the tablet into the capsule body			
Station 4	To fill the tablet into the capsule body			
Station 5	To fill the part into the capsule body			
Station 6	To fill the tablet into the capsule body			
Station 7	To reject the un separated capsules			
Station 8	Downward movement of upper segment and backward movement of bottom segment			
Station 9	Idle station			
Station 10	To lock the capsule			
Station 11	To Eject the filled capsule			
Station 12	To clean and remove the loose powder inside the segment by vacuum and compressed air			
2. Hopper assembly				
Powder hopper	For storage of the powder			

Name of system component	Specified function	Observation	Method of verification	Verified by (Sign/date)
Auger	To feed the powder from hopper to dosing drum			
Lead screw	To lifting and lowering the powder assembly			
3. Tablet Filling Attachment				
Vibratory plate	To orient and transfer the tablets into the magazine			
Sliding plate	To transfer the tablet into the lower fix block			
4. Loader Assembly				
Loader Body With Magazine	To provide Capsules from hopper to slots of the raceway			
Pusher block	To orient the capsule on the raceway in Cap up and body down position			
Finger block	To release the capsule with cap up and body down position			
Horizontal finger assembly	Turn hand wheel and check free movements of finger assembly in guides through its Stroke. Finger should not rub against its faces			
	Movement of the fingers to be through visual center of segment block slot. The finger shouldn't move in cross directions.			

Name of system component	Specified function	Observation	Method of verification	Verified by (Sign/date)
	Capsule should be rectified and pushed forward in the segment upto such a position that during the downward stroke of the magazine, vertical fingers will strike the cap portion 1 mm from the junction of cap and body.			
	After finger push capsule forward, there shouldn't be any stretch marks on capsule, especially cap which is caused by rough edges of the rectifier.			
Vertical fingers assembly	Finger profile should guide empty capsule effectively and smoothly. The capsule should fall dead straight into the segment.			
	Check gap between bottom edge of vertical finger and cup bush holder after cap bush holder moves up, to be 0.75 ±0.25 mm			
	Check free movement of the release finger in the magazine slot.			
Capsule release mechanism	Release liver should have 2 positions, 1 for releasing and 2 for stopping capsule flow.			

Name of system component	Specified function	Observation	Method of verification	Verified by (Sign/date)
	Check movement of release fingers. None of them should touch the magazine of the loader lever throughout its full stroke.			
	No vacuum leakage through grommets or connections.			
	Check vacuum sequence. After capsules falls from rectifier block into the bush holder, vacuum should come ON.			
Vacuum Separation Block Assembly.	Ensure that there is no capsule / powder chip in the vacuum filter on top segment.			
Trials with empty capsules	Load empty capsules in the capsule hopper. There should be no static charge on capsules. Adjust the capsule empty control flap to a pilot position start the machine.			
	Ensure proper functioning of vacuum gauge.			
	Check for proper uniform flow of capsules in the magazine.			
	Capsule should get properly loaded in segment without crushing.			
	Check proper entry of capsules in the magazine			
	Check proper release of capsules in segment (one at a time)			
	Check proper separation of cap/body			

Name of system component	Specified function	Observation	Method of verification	Verified by (Sign/date)
	Removal of unopened capsules inside the unopened capsule box with compressed air.			
	Check closing of capsules without denting / telescoping			
	Closed joint of the capsule to be set as per table.			
	Size # 2 1.4 mm Closed joint length (±0.4 mm)	Actual _____ mm		
	Check proper ejection of capsules through exit chute without crushing.			
	Stop the machine and count the number of rejected capsules from each stations Rejected capsules on the machine surface to be less then 1% inclusive all the defects. (for machine related errors only)			

Name of system component	Specified function	Observation	Method of verification	Verified by (Sign/date)
	Details of rejected capsules: A) Double capsule loaded in Segment B) Crushed during loading. C) Cap pop up. D) Body crushed during separation of body and cap E) Unopened capsules. F) Crushed during closing. G) Crushed during ejection. H) Others (Specify) **Total**	_____ Nos. _____Nos. _____ Nos. _____ Nos. _____ Nos. _____ Nos. _____ Nos. _____ Nos. _____ Nos.		
5. Powder Assembly				
Tamping punch/pins	To tamp the powder at 5th and 6th station			
6. Powder filling operations	Rest all tamping position for stations 1 – 6 on support pad. All scales should “0” reading.	1 2 3 4 5 6 __ __ __ __ __ __		
	Powder should flow properly in all parts of the dosing disc. Adjust gate flap and sensor to ensure sufficient powder & uniform distribution of powder in tub.			

Name of system component	Specified function	Observation	Method of verification	Verified by (Sign/date)
	Fill a batch of 1000 capsules and check for a) Denting b) Telescoping. c) Unlocked d) Folded	_____ Nos. _____ Nos. _____ Nos. _____ Nos.		
	Check weight variation	Avg. wt. _____ mg		
6. Unopened Capsule Collection Assembly.				
	Check air jet from each hole of air jet block.			
	Ensure ejection pin's don't scratch cap bushes. Check bush inner face.			
	Pins to be in center of bushes.			
	Stop vacuum and start capsules. All unopened capsules to be ejected to and collected in unopened box & no capsule to spill outside or get stuck.	100% ejected & collected ____Nos. not ejected or damaged.		

7. Capsule Locking Assembly				
Locking pins	To lock the filled capsule			
9. Capsule Locking Assembly.	Pins to be in center of the bush.			
	Ensure closing pins don't stretch body bushes. Check bush inner face.			

	Ensure closing length of all capsules are within a segment within ±0.4 mm. (All 9 capsules / segments)			
8. Ejection Assembly				
Ejection Pins	To Eject the filled capsule in to the outlet chute			
Capsule Ejection assembly.	Check alignment of the guide plate and bush holder (Visual Center)			
	Ensure uniform airjet from each block of airjet block.			
	Ejection pin should come out by 2-2.5 mm from guide hole.			
	Ensure ejection pin don't stretch cap bushes. Check bush inner face.			

9. BRAKE FUNCTIONALITY TEST				
De-select the auto mode & manual mode from the main screen	Brake coil gets energized and releases the motor.			
Either auto mode or manual mode is selected	Brake coil gets de-energized and holds the motor shaft.			
10. VACUUM PUMP FUNCTIONALITY TEST				
Press the vacuum pump key on the manual mode screen	Vacuum pump starts and the text on the key displays ON			
Press the vacuum key again on the manual mode screen	Vacuum pump stops and text on the key displays OFF			
11. BLOWER FUNCTIONALITY TEST				
Press blower key on the manual mode screen	Blower starts and the text on the key displays ON			
Press the blower key again on the manual mode screen	Blower stops and the text on the key displays OFF			
12. LOADER SOV FUNCTIONALITY TEST				
Press the loader SOV key on the manual mode screen	The pneumatic cylinder for the loader assembly gets actuated and the text on the key displays ON			
Press the loader SOV key on the manual mode screen	The pneumatic cylinder for the loader assembly gets OFF and the text on the key displays OFF			
13. MAIN MOTOR INCH FUNCTIONALITY TEST				

Keep the M/C Inch key pressed on the manual mode screen	Main motor starts in inch mode till the key is kept pressed and text on the key displays ON			
Release M/C Inch key on the manual mode screen	Main motor stops and text on the key displays OFF			
14. AUGER MOTOR FUNCTIONALITY TEST				
Keep the Auger Inch key pressed on the manual mode screen	Auger motor starts in inch mode till key is kept pressed and text on key displays ON			
Release Auger Inch key on the manual mode screen	Auger motor stops and text on the key displays OFF			
15. MAIN MOTOR FUNCTIONALITY TEST				
Press the start key on the auto mode screen	Machine starts in auto mode			
Press the stop key on the auto mode screen	Machine stops in auto mode			

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

Reviewed by (Sign/Date)

5.6 VERIFICATION OF KEY FUCTIONALITY OF CONTROL PANEL:

COMPONENT OF CONTROL PANEL	SPECIFIED FUNCTION	OBSERVATION	VERIFIED BY (SIGN/DATE)
Main Switch	To supply the power into the machine		
Buzzer	To indicate the alarm message		
PLC	To control all the function of the capsule filling machine		
Emergency stop switch	To stop the machine in case of emergency		

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

Reviewed by (Sign/Date)

5.7 VERIFICATION OF SAFETY FEATURES, ALARMS AND INTERLOCKS:

Interlock Features Description	Features Description Alarm/ Messages Effect on function	Observation	Checked by (Sign/date)
Safety Features			
Emergency switch	To stop the machine in case of emergency		
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.		
Motor overload Relay	For Motor & equipment protection.		

Interlock Features			
PASSWORD CHECK:			
Enter any random password other than the correct password for Level - I on the Power On screen after Login key is pressed	No message will appear on the HMI. However the user will be prompted to re-enter the password.		
Enter the correct password for Level	The message "**OK, level is 1**" will appear on the HMI.		

Enter correct password for Level – II after pressing the Login key on the Power On screen	The message "**OK, level is 2**" will appear on the HMI.		
Enter correct password for Level – III after pressing the Login key on the Power On screen	The message "**OK, level is 3**" will appear on the HMI.		
EMERGENCY STOP CHECK:			
Press the Emergency Push button on the Operating Panel	The message "**EMERGENCY STOP OPERATED**" will appear on the alarm screen of HMI		
Press the machine inch key on the Manual mode Screen	Blower Motor will not start even after Machine inch key is pressed		
Release the emergency stop push button on the operating panel	The '*' sign before the alarm text will disappears and on acknowledging the alarm the color of the text changes		
Press the machine inch key on the Manual mode Screen	Machine starts till the key is kept pressed		
MAIN AIR PRESSURE:			
Cutoff the main air pressure	The message "AIR PRESSURE NOT OK" will appear on the alarm screen of the HMI		
Press the start key on the auto mode screen	The main motor will not start		

Connect the main air pressure line	The '*' sign before alarm message disappears and on acknowledging the color of the text disappears		
Press the start key on the auto mode screen	The main motor starts		
VACUUM PUMP MOTOR / BLOWER MOTOR TRIP / AUGER MOTOR TRIP CHECK			
Press the test key on the overload relay of vacuum pump motor of blower motor or auger motor	The message "PUMP / BLOWER / AUGER MOTOR TRIP" will appear on the alarm screen of the HMI		
Press the start key on the auto mode screen	The main motor will not start		
Press the reset key on the O/L relay of vacuum pump, blower & auger motor	The '*' sign before the message disappears and on acknowledging the color of the message changes		
Press the start key on the auto mode screen	The machine starts		
CAPSULE LEVEL LOW CHECK:			
During the running of the machine place the capsule low level sensor away from the capsules for more than 60 sec	The message "CAPSULE LEVEL LOW" will be displayed on the alarm screen of the HMI		
Press the start key on the auto mode screen	The machine will not start		
Place the sensor in front of the capsules	The '*' sign in front of the sensor will disappear and on acknowledging the alarm, the colour of the alarm text will change		

Press the start key on the auto mode screen	The main motor starts		
POWDER LEVEL LOW CHECK:			
During the running of the machine when the powder station is selected and powder sensor remains OFF for more than 30 sec	The message “POWDER LEVEL LOW” will appear on the alarm screen		
Press the start key on the auto mode screen	The main motor does not start		
Place the sensor in front of the powder sensor or de-select the powder sensor	The ‘*’ sign before the alarm text disappears and on acknowledging the alarm, the colour of the text changes		
Press the start key on the auto mode screen	The main motor starts		

SAFETY DOOR CHECK:			
During the running of the machine, lift the acrylic door	The message “SAFETY DOOR OPEN” will be displayed on the alarm screen of the HMI		
Press the start key on the auto mode screen	The main motor does not start		
Close the acrylic safety door	The ‘*’ sign before the alarm text disappears and on acknowledging the alarm, the color o the text changes		
Pres the start key on the auto mode screen	The main motor starts		
VACUUM LEVEL LOW CHECK:			
During the running of the machine if the vacuum sensor remains OFF for more than 5 sec	The message “VACUUM LEVEL LOW” will appear on the alarm screen of the HMI		
Press the start key on the auto mode screen	The ‘*’ sign before the alarm text disappears and on acknowledging the alarm, color of the text changes and The main motor will start		
The vacuum switch gets ON within 5 sec	The machine will continue running		

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

Reviewed by (Sign/Date)

5.8 VERIFICATION 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)

5.9 VERIFICATION OF STANDARD OPERATING PROCEDURE (SOP)

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

S.No.	SOP TITLE	SOP NUMBER	VERIFIED BY DATE

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

Reviewed by (Sign/Date)

5.10 TRAINING RECORD OF PERSONNEL (S) :

S.No.	Name of Personnel	Designation	Sign. & Date	Trained By	Remark

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

Reviewed by (Sign/Date)

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

Following deficiency was verified and corrective actions taken in consultation with the Engineering Department.

Description of deficiency:

Corrective action(s) taken:

Deviation accepted by
(Sign/Date)

Deviation Approved by
(Sign/Date)

5.12 Annexure (S)

Annexure No.	Details of Annexure

Remarks (if any)**:**

_____

_____

_____

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

6.0 OPERATIONAL QUALIFICATION FINAL 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		