



PHARMA DEVILS

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

PROTOCOL No.:

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1.0 SYSTEM INFORMATION

Manufacturer	Regd. Office: -	Works: -
Customer		
Site		

Protocol Prepared By

Name of the Manufacturer	Signing Authority & Designation	Signature	Date

Protocol Approved By

Name of the Customer	Signing Authority & Designation	Signature	Date



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2.0 OBJECTIVE

- 2.1. The Operational Qualification Protocol (hereafter referred to as 'OQ') shall demonstrate the complete operation 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 operational specifications laid down in this protocol.

3.0 SCOPE

- 3.1 The scope of this OQ shall be confined to Pharmafill A120.
- 3.2 The Qualification of any additional accessories apart from those specified in this OQ 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 OQ.
- 3.4 The equipment shall be intended for filling powder 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 deg C.



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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 OQ incorporating the following major parameters:

- PLC, I/P and O/P functionality checks.
- HMI Accessibility checks.
- Various operational and functionality checks.
- Interlock functionality checks.
- Power failure and restoration test


4.1.3 To assist the Customer to carry out the OQ at the site.

4.2 Customer

4.2.1 To verify the OQ.

4.2.2 To approve the OQ

4.2.3 To carry out the OQ at the site.

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5.0 FUNCTIONAL VERIFICATION OF OPERATIONAL AND FUNCTIONALITY CHECKS

NOTE: PRESS THE MANUAL MODE DISABLED TO ENABLE MANUAL MODE.

VACUUM PUMP FUNCTIONALITY TEST

S. No.	Simulation Methodology	Acceptance Criteria	Observation	Remarks
1.	Press the VACUUM PUMP OFF function key on the manual mode screen	Vacuum pump will start		
2.	Press the VACUUM PUMP ON key again on the manual mode screen	Vacuum pump will get stop		

MAIN MACHINE BLOWER FUNCTIONALITY TEST

S. No.	Simulation Methodology	Acceptance Criteria	Observation	Remarks
1.	Press the BLOWER OFF function key on Manual screen	Main machine de dusting blower Motor will start		
2.	Press the BLOWER ON function key on Manual screen	Main machine de dusting blower Motor will stop		

ECSE MACHINE FUNCTIONALITY TEST

S. No.	Simulation Methodology	Acceptance Criteria	Observation	Remarks
1.	Press the ECSE MACHINE OFF function key on Manual screen	ECSE Machine blower Motor will start		
2.	Again Press the ECSE MACHINE ON function key on Manual screen	ECSE Machine blower Motor will stop		

MACHINE INCH FUNCTIONALITY TEST

S. No.	Simulation Methodology	Acceptance Criteria	Observation	Remarks
1.	Keep the MACHINE Inch key pressed on the manual mode screen	Machine starts in inch mode till the key is kept pressed		
2.	Release MACHINE Inch key on the manual mode screen	Machine will stop		



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STIRRER MOTOR FUNCTIONALITY TEST

S. No.	Simulation Methodology	Acceptance Criteria	Observation	Remarks
1.	Keep the STIRRER Inch key pressed on the manual mode screen	Stirrer motor starts in inch mode till key is kept pressed		
2.	Release STIRRER Inch key on the manual mode screen	Stirrer motor stops		

LOADER -1 FUNCTIONALITY TEST

S. No.	Simulation Methodology	Acceptance Criteria	Observation	Remarks
1.	Press the LOADER -1 function_key on the manual mode screen	The pneumatic cylinder for the loader-1 assembly gets actuated		
2.	Again Press the LOADER -1_key on the manual mode screen	The pneumatic cylinder for the loader-1 assembly gets OFF		

LOADER -2 FUNCTIONALITY TEST

S. No.	Simulation Methodology	Acceptance Criteria	Observation	Remarks
1.	Press the LOADER -2 function key on the manual mode screen	The pneumatic cylinder for the loader-2 assembly gets actuated		
2.	Again Press the LOADER -2 function key on the manual mode screen	The pneumatic cylinder for the loader -2 assembly gets OFF		

VIBRATOR- 1 INCH FUNCTIONALITY TEST

Note: Tablet -1 should be selected (OPERATION SCREEN)

S. No.	Simulation Methodology	Acceptance Criteria	Observation	Remarks
1.	Keep the VIBRATOR- 1 INCH key pressed on the manual mode screen	Tablet station 1 vibrator will starts in inch mode till key is kept pressed		
2.	Release VIBRATOR- 1 INCH key on the manual mode screen	Tablet station 1 vibrator will stops		



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VIBRATOR- 2 INCH FUNCTIONALITY TEST

Note: Tablet -2 should be selected (OPERATION SCREEN)

S. No.	Simulation Methodology	Acceptance Criteria	Observation	Remarks
1.	Keep the VIBRATOR- 2 INCH key pressed on the manual mode screen	Tablet station 2 vibrator starts in inch mode till key is kept pressed		
2.	Release VIBRATOR- 2 INCH key on the manual mode screen	Tablet station 2 vibrator stops		

STATION 1 TABLET PUSH FUNCTIONALITY TEST

Note: Tablet releasing plate should complete its stroke (manually operate machine inch & complete its stroke)

S. No.	Simulation Methodology	Acceptance Criteria	Observation	Remarks
1.	Press the STATION 1 TABLET PUSH function key on the manual mode screen	Tablet station 1 tablet release plate will operate in forward direction & complete full stroke		
2.	Again Press the STATION 1 TABLET PUSH function key on the manual mode screen	Tablet station 1 tablet release plate will operate in backward direction		

STATION 2 TABLET PUSH FUNCTIONALITY TEST

Note: Tablet releasing plate should complete its stroke (manually operate machine inch & complete its stroke)

S. No.	Simulation Methodology	Acceptance Criteria	Observation	Remarks
1.	Press the STATION 2 TABLET PUSH function key on the manual mode screen	Tablet station 2 tablet release plate will operate in forward direction & complete full stroke		
2.	Again Press the STATION 2 TABLET PUSH function key on the manual mode screen	Tablet station 2 tablet release plate will operate in backward direction		



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MAIN MACHINE (AUTO MODE) FUNCTIONALITY TEST

NB: - All interlocks should be OK

S. No.	Simulation Methodology	Acceptance Criteria	Observation	Remarks
1.	Press the start key on the auto mode screen	Machine starts in auto mode i.e. Main Machine, Vacuum Pump & De dusting Blower will start		
2.	Press on TOTAL RESET	Total production data will be zero		
3.	Press on DAY RESET	Day production data will be zero		
4.	Press on TIME RESET	Machine run time will be zero		
5.	Press the stop key on the auto mode screen	Machine stops in auto mode i.e. Main Machine, Vacuum Pump & De dusting Blower will stop		



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SAMPLING SCREEN

S. No.	Simulation Methodology	Acceptance Criteria	Observation	Remarks
1.	Select Manual mode of sampling after filling data press on TAKE SAMPLE	Fill the following data 1) Require Segment Sample 2) Manual Sampling Segment Number 3) Number of Segments to be Sampled 4) Delay Time for Next Segment Sample Capsule samples will be collected of the respective segment number		
2.	Select Auto mode of sampling after filling data press on TAKE SAMPLE	Capsule samples will be collected from station no 1 to station no 12 after each turret rotation		



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6.0 FUNCTIONAL VERIFICATION OF SAFETY INTERLOCK CHECKS

N.B.: External simulation of the sensors should be done.

Test	Acceptance Criteria		Observation	Remarks
	Alarm/ Messages	Effect on function		
PASSWORD CHECK:				
Enter any random password other than the correct password for Level	“Invalid user name or Password” message will appear on the HMI. However the user will be prompted to re-enter the correct password.	NA		
Enter the correct password for Level 1 i.e. “1234”	The message “ User OPERATOR is logged In ” will appear on the HMI.	NA		
Enter correct password for Level – 2 i.e. “2345”	The message “ User SUPERVISOR is logged In ” will appear on the HMI.	NA		
Enter correct password for Level – 3 i.e. “3456”	The message “ User ENGINEER_ MANAGER is logged In ” will appear on the HMI.	NA		
Enter correct password for Level – 4 i.e. “3456”	The message “ User ADMINISTRATOR logged in ” will appear on the HMI.	NA		
EMERGENCY STOP CHECK:				
Press the start key on the auto mode screen	NA	The machine will start		
Press the Emergency Push button on the Operating Panel	The message “ EMERGENCY STOP PRESSED ” will appear on the alarm screen of HMI	Machine will get stop		
Release the emergency stop push button on the operating panel & Press Alarm Acknowledgement and Alarm Reset function key on Alarm screen	The Color of the highlighted alarm will change from red to yellow.	The machine will get reset		
AIR PRESSURE NOT OK:				



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Test	Acceptance Criteria		Observation	Remarks
	Alarm/ Messages	Effect on function		
Press the start key on the auto mode screen	NA	The main motor starts		
Cutoff the main air pressure	The message “ MAIN AIR PRESSURE NOT OK ” will appear on the alarm screen of the HMI	The Machine will get stop.		
Reconnect the main air pressure line & Press Alarm Acknowledgement and Alarm Reset function key on Alarm screen	The Color of the highlighted alarm will change from red to yellow.	The machine will get reset		
VACUUM PUMP OVERLOAD				
Press the start key on the auto mode screen	NA	The main motor starts		
Press the test key on the overload relay of vacuum pump	The message “ VACUUM PUMP OVERLOAD ” will appear on the alarm screen of the HMI	The Machine will get stop.		
Press the reset key on the O/L relay of vacuum pump & Press Alarm Acknowledgement and Alarm Reset function key on Alarm screen	The Color of the highlighted alarm will change from red to yellow.	The machine will get reset		
BLOWER MOTOR OVERLOAD				
Press the start key on the auto mode screen	NA	The main motor starts		
Press the test key on the overload relay of blower motor	The message “ BLOWER MOTOR OVERLOAD ” will appear on the alarm screen of the HMI	The Machine will get stop.		



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	Alarm/ Messages	Effect on function		
Press the reset key on the O/L relay of blower motor & Press Alarm Acknowledgement and Alarm Reset function key on Alarm screen	The Color of the highlighted alarm will change from red to yellow.	The machine will get reset		
STIRRER MOTOR OVERLOAD :				
Press the start key on the auto mode screen	NA	The main motor starts		
Press the test key on the overload relay of Auger motor	The message “AUGER MOTOR OVERLOAD” will appear on the alarm screen of the HMI	The Machine will get stop.		
Press the reset key on the O/L relay of Auger Motor & Press Alarm Acknowledgement and Alarm Reset function key on Alarm screen	The Color of the highlighted alarm will change from red to yellow.	The machine will get reset		
CAPSULE LEVEL LOW CHECK:				
During the running of the machine place the capsule low level sensor away from the capsules for more than set time in sec	The message “CAPSULE LEVEL LOW” will be displayed on the alarm screen of the HMI	The main motor starts		
Place the sensor in front of the capsules & Press Alarm Acknowledgement and Alarm Reset function key on Alarm screen	The Color of the highlighted alarm will change from red to yellow.	The machine will get reset		
POWDER LEVEL LOW CHECK:				
During the running of the machine when the powder station is selected and powder sensor remains OFF for more than set time in sec	The message “POWDER LEVEL LOW” will appear on the alarm screen	The main motor stops		



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	Alarm/ Messages	Effect on function		
Place the sensor in front of the powder or de-select the powder sensor & Press Alarm Acknowledgement and Alarm Reset function key on Alarm screen	The Color of the highlighted alarm will change from red to yellow.	The machine will get reset		
SAFETY DOOR CHECK:				
During the running of the machine, lift the acrylic door	The message “ SAFETY DOOR OPENED ” will be displayed on the alarm screen of the HMI	The main motor stops		
Close the acrylic safety door & Press Alarm Acknowledgement and Alarm Reset function key on Alarm screen	The Color of the highlighted alarm will change from red to yellow.	The machine will get reset		
VACUUM SWITCH -1 / 2 NOT OK:				
Press the start key on the auto mode screen	NA	The main motor starts		
During the running of the machine if the vacuum sensor remains OFF for more than 5 sec	The message “ VACUUM SWITCH 1 OR VACUUM SWITCH 2 NOT OK ” will appear on the alarm screen of the HMI	The Machine will get stop.		
The vacuum switch gets ON within 5 sec & Press Alarm Acknowledgement and Alarm Reset function key on Alarm screen.	The Color of the highlighted alarm will change from red to yellow.	The machine will get reset		
MAIN MOTOR VFD FAULT:				
Press the start key on the auto mode screen	NA	The Main Motor will start		
Switch Off the MCB for main motor	The message “ MAIN MOTOR OVERLOAD ” will appear on the HMI	Main Motor will stop		



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	Alarm/ Messages	Effect on function		
Switch ON the MCB for main motor & Press Alarm Acknowledgement and Alarm Reset function key on Alarm screen	The Color of the highlighted alarm will change from red to yellow.	The machine will get reset		
PHASE FAILURE CHECK:				
Press the start key on the auto mode screen	NA	The Main Motor will start		
Remove the input cable from the phase preventer relay	The message “ PHASE FAILURE ” will appear on the HMI	Main Motor will stop		
Reconnect the input cable from the phase preventer relay & Press Alarm Acknowledgement and Alarm Reset function key on Alarm screen	The Color of the highlighted alarm will change from red to yellow.	The machine will get reset		
PELLET LEVEL LOW CHECK:				
Press the start key on the auto mode screen	NA	The main machine will start at the set speed		
During the running of the machine when the pellet station – 1or2or3 is selected and pellet sensor remains OFF for more than set time	The message “ PELLET STATION - 1 LEVEL LOW OR PELLET STATION - 2 LEVEL LOW OR PELLET STATION - 3 LEVEL LOW OR ” will appear on the alarm screen	Machine will stop		



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Test	Acceptance Criteria		Observation	Remarks
	Alarm/ Messages	Effect on function		
Place the sensor in front of the pellet sensor or de-select the pellet sensor And press ALARM RESET key on alarm screen	The Color of the highlighted alarm will change from red to yellow.	Alarm will get reset.		
CHECK STN1/2 TABLET /TABLET FEEDING SENSOR :				
During the running of the machine if the Tablet sensor remains OFF for less than 5 times continuously i.e. tablet not got filled in capsule	NA	Respective capsule will get rejected & collected in Reject capsule collection bin		
During the running of the machine if the Tablet sensor remains OFF for more than 5 times continuously	The message “CHECK STN 1 TABLETS / TABLET FEEDING SENSOR OR CHECK STN 2 TABLETS / TABLET FEEDING SENSOR” will appear on the alarm screen of the HMI	Machine will get stop		
Feed the tablets into respective the vibratory bowl	NA	Alarm will get reset		



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8.0 PARTICIPANT LOG

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

Name	Designation	Department	Signature with Date

9.0 ATTACHMENT LOG

All documents attached to this protocol should be listed in following log. If the attachment is more than one page then denote the number of pages along with the protocol number, signature and date on the first page of the attachment.

S.No.	Attachment	Total No. of Pages	Signature with Date	Remarks

10.0 VARIATIONS

Should there be any addition / modification in the OQ 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.

