

### TABLE OF CONTENTS

S.No.	Content	Page No.
1.	System Information	2
2.	Objective	3
3.	Scope	3
4.	Responsibilities	4
5.	Functional verification of Various Operational and functionality checks	5
6.	Functional verification of various safety Interlock checks	11
7.	Power failure and restoration test	18
8.	Participant Log	19
9.	Attachment log	19
10.	Variations	20
11.	Review and comments	20
12.	Abbreviations	20
13.	Approval sheet from Customer	21



PROTOCOL No.:

Manufacturer	Regd. Office: -	Works: -
Customer		
Customer		
S:40		
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



### 2.0 **OBJECTIVE**

- The Operational Qualification Protocol (hereafter referred to as 'OQ') shall demonstrate the 2.1. 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**

- The scope of this OQ shall be confined to Pharmafill A120. 3.1
- 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.



4.0

4.1

# **OPERATIONAL QUALIFICATION PROTOCOL** FOR AUTOMATIC CAPSULE FILLING MACHINE WITH POWDER,

# PELLET AND TABLET FILLING ATTACHMENT

To ensure that the equipment manufactured is in line with the DQ.

To prepare the OQ incorporating the following major parameters:

HMI Accessibility checks. • Various operational and functionality checks. • Interlock functionality checks. •

RESPONSIBILITIES Manufacturer

•

4.1.1

4.1.2

- Power failure and restoration test •
- 4.1.3 To assist the Customer to carry out the OQ at the site.

PLC, I/P and O/P functionality checks.

### 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.



**PROTOCOL No.:** 

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



# **OPERATIONAL QUALIFICATION PROTOCOL** FOR AUTOMATIC CAPSULE FILLING MACHINE WITH POWDER,

**PROTOCOL No.:** 

PELLET AND TABLET FILLING ATTACHMENT

# STIRRER MOTOR FUNCTIONALITY TEST

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

### **LOADER -1 FUNCTIONALITY TEST**

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

### **LOADER -2 FUNCTIONALITY TEST**

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

### **VIBRATOR- 1 INCH FUNCTIONALITY TEST**

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

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



### VIBRATOR- 2 INCH FUNCTIONALITY TEST

**PROTOCOL No.:** 

	Note: Tablet -2 should be selected (OPERATION SCREEN)				
S.	S. Simulation Methodology Acceptance Observation Re				
No.		Criteria			
1.	Keep the VIBRATOR-2	Tablet station 2			
	INCH key pressed on the	vibrator starts in			
	manual mode screen	inch mode till key			
		is kept pressed			
2.	Release VIBRATOR- 2	Tablet station 2			
	INCH key on the manual	vibrator stops			
	mode screen				

### STATION 1 TABLET PUSH FUNCTIONALITY TEST

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

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

### STATION 2 TABLET PUSH FUNCTIONALITY TEST

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

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



MAIN MACHINE (AUTO MODE) FUNCTIONALITY TEST

NB: - All interlocks should be OK

S.	Simulation Methodology	Acceptance	Observation	Remarks
No.		Criteria		
1.	1. Press the start key on the Machine starts in			
	auto mode screen	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.	5. Press the stop key on the Machine stops in			
	auto mode screen	auto mode i.e. Main		
		Machine, Vacuum		
		Pump & De dusting		
		Blower will stop		



# SAMPLING SCREEN

S.	S. Simulation Methodology Acceptance		Observation	Remarks
No.		Criteria		
1.	Select Manual mode of sampling after filling data press on TAKE SAMPLE	<ul> <li>Fill the following data</li> <li>1) Require Segment Sample</li> <li>2) Manual Sampling Segment Number</li> <li>3) Number of Segments to be Sampled</li> <li>4) Delay Time for Next Segment Sample</li> <li>Capsule samples</li> </ul>		
	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		



### 6.0 FUNCTIONAL VERIFICATION OF SAFETY INTERLOCK CHECKS

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

	Acceptance Criteria			
Test	Alarm/ Messages	Effect on function	Observation	Remarks
PASSWORD CHEC	CK:	•		
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	NA		
Enter the correct password for Level 1 i.e. "1234"	the correct password. 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 STO	OP 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		



relay of blower

motor

MOTOR

**OVERLOAD**" will appear on the alarm screen of the HMI

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

Effect on

Acceptance Criteria

**PROTOCOL No.:** 

Remarks

Observation

1050	Alarm/ Messages	Effect on function		i i i i i i i i i i i i i i i i i i i
Press the start key	NA	The main		
on the auto mode		motor starts		
screen				
Cutoff the main air	The message <b>"MAIN</b>	The Machine		
pressure	AIR PRESSURE	will get stop.		
-	NOT OK" will			
	appear on the alarm			
	screen of the HMI			
Reconnect the main	The Color of the	The machine		
air pressure line &	highlighted alarm	will get reset		
Press Alarm	will change from red			
Acknowledgement	to yellow.			
and Alarm Reset				
function key on				
Alarm screen				
VACUUM PUMP (	OVERLOAD			1
Press the start key		The main		
on the auto mode	NA	motor starts		
screen				
Press the test key	The message	The Machine		
on the overload	"VACUUM PUMP	will get stop.		
relay of vacuum	OVERLOAD" Will			
pump	appear on the alarm			
Due en (1- e	The Color of the	The second is a		
press the reset key	highlighted elerm	The machine		
on the O/L relay of	mgninghted alarm	will get reset		
Pross Alarm	to vallow			
Acknowledgement	to yellow.			
and Alarm Reset				
function key on				
Alarm screen				
<b>BLOWER MOTOR</b>	R OVERLOAD	1	1	1
Press the start key		The main		
on the auto mode	NA	ne main motor storts		
screen		motor starts		
Press the test key	The message	The Machine		
on the overload	<b>"BLOWER</b>	will get stop.		



During the running

of the machine

in sec

when the powder station is selected

and powder sensor remains OFF for more than set time

The message

**"POWDER LEVEL** 

LOW" will appear

on the alarm screen

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

Effect on

function

**Acceptance Criteria** 

Alarm/ Messages

**PROTOCOL No.:** 

Remarks

Observation

Press the reset key	The Color of the	The machine		
on the O/L relay of	highlighted alarm	will get reset		
blower motor &	will change from red	-		
Press Alarm	to yellow.			
Acknowledgement				
and Alarm Reset				
function key on				
Alarm screen				
STIRRER MOTOR	R OVERLOAD :			
Press the start key		The main		
on the auto mode	NA	motor starts		
screen				
Press the test key	The message	The Machine		
on the overload	<b>"AUGER MOTOR</b>	will get stop.		
relay of Auger	<b>OVERLOAD</b> " will			
motor	appear on the alarm			
	screen of the HMI			
Press the reset key	The Color of the	The machine		
on the O/L relay of	highlighted alarm	will get reset		
Auger Motor &	will change from red			
Press Alarm	to yellow.			
Acknowledgement				
and Alarm Reset				
function key on				
Alarm screen				
CAPSULE LEVEL	LOW CHECK:	1		r
During the running	The message	The main		
of the machine	"CAPSULE	motor starts		
place the capsule	LEVEL LOW" will			
low level sensor	be displayed on the			
away from the	alarm screen of the			
capsules for more	HMI			
than set time in sec				
Place the sensor in	The Color of the	The machine		
front of the	highlighted alarm	will get reset		
cansules & Press	will change from red	1		

on the O/L relay of Auger Motor &	highlighted alarm will change from red	will get reset	
Press Alarm	to yellow.		
Acknowledgement			
and Alarm Reset			
function key on			
Alarm screen			
CAPSULE LEVEL	LOW CHECK:		 -
During the running	The message	The main	
of the machine	"CAPSULE	motor starts	
place the capsule	LEVEL LOW" will		
low level sensor	be displayed on the		
away from the	alarm screen of the		
capsules for more	HMI		
than set time in sec			
Place the sensor in	The Color of the	The machine	
front of the	highlighted alarm	will get reset	
capsules & Press	will change from red		
Alarm	to yellow.		
Acknowledgement			
and Alarm Reset			
function key on			
Alarm screen			
POWDER LEVEL	LOW CHECK:		

The main

motor stops



Test

Place the sensor in

front of the powder

or de-select the

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

Effect on

function

The machine

will get reset

**Acceptance Criteria** 

Alarm/ Messages

The Color of the

highlighted alarm

will change from red

**PROTOCOL No.:** 

Remarks

Observation

powder sensor &	to yellow.		
Press Alarm			
Acknowledgement			
and Alarm Reset			
function key on			
Alarm screen			
SAFETY DOOR CL	HECK:		 -
During the running	The message	The main	
of the machine, lift	<b>"SAFETY DOOR</b>	motor stops	
the acrylic door	<b>OPENED</b> " will be		
	displayed on the		
	alarm screen of the		
	HMI		
Close the acrylic		The machine	
safety door & Press	The Color of the	will get reset	
Alarm	highlighted alarm		
Acknowledgement	will change from red		
and Alarm Reset	to vellow		
function key on	to yenow.		
Alarm screen			
VACUUM SWITCH	H -1 / 2 NOT OK:	•	 •
Press the start key	NA	The main	
on the auto mode		motor starts	
screen			
During the running	The message	The Machine	
of the machine if	"VACUUM	will get stop.	
the vacuum sensor	SWITCH 1 OR		
remains OFF for	VACUUM		
more than 5 sec	SWITCH 2 NOT		
	OK" will appear on		
	the alarm screen of		
	the HMI		
The vacuum switch	The Color of the	The machine	
gets ON within 5	highlighted alarm	will get reset	
sec & Press Alarm	will change from red		
Acknowledgement	to vellow.		

### Alarm screen. MAIN MOTOR VFD FAULT:

and Alarm Reset function key on

Press the start key		The Main	
on the auto mode	NA	Motor will	
screen		start	
Switch Off the	The message "MAIN	Main Motor	
MCB for main	MOTOR	will stop	
motor	<b>OVERLOAD</b> " will	_	
	appear on the HMI		



Switch ON the

MCB for main

motor & Press

Acknowledgement and Alarm Reset function key on Alarm screen

Alarm

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

Alarm/ Messages

PROTOCOL No.:

Remarks

Acceptance Criteria Observation Effect on function

The Color of the The machine highlighted alarm will get reset will change from red to yellow.

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



Feed the tablets

vibratory bowl

into respective the

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

Effect on

Acceptance Criteria

Alarm/ Messages

TABLET FEEDING SENSOR" will appear on the alarm screen of the HMI

NA

**PROTOCOL No.:** 

Remarks

Observation

Alariii/ Messages		function			
Place the sensor in	The Color	of the	Alarm will		
front of the pellet	highlighted	alarm	get reset.		
sensor or de-select	will change	from red			
the pellet sensor	to yellow.				
And press ALARM					
RESET key on					
alarm screen					
CHECK STN1/2 TA	BLET /TAB	LET FEE	DING SENSOI	R :	1
During the running	NA		Respective		
of the machine if			capsule will		
the Tablet sensor			get rejected		
remains OFF for			& collected		
less than 5 times			in Reject		
continuously i.e.			capsule		
tablet not got filled			collection		
in capsule			bin		
During the running	The message		Machine will		
of the machine if	<b>"CHECK S</b>	ΓN 1	get stop		
the Tablet sensor	TABLETS /				
remains OFF for	TABLET				
more than 5 times	FEEDING				
continuously	SENSOR O	R			
2	CHECK ST	N 2			
	TABLETS /				

Alarm will

get reset



### 7.0 POWER FAILURE AND RESTORATION TEST

### 7.1 **Procedure:**

- 7.1.1 Start the machine in its standard starting procedure.
- 7.1.2 Trip the main incoming power supply, thereby simulating for Pseudo Power Failure.
- Wait for some time and Switch ON the main incoming power supply 7.1.3

### 7.2 **Acceptance Criteria:**

- 7.2.1 The machine should not start until and unless it is started manually.
- 7.2.2 No Data should be erased.

### 7.3 **Observation:**





### **PARTICIPANT LOG** 8.0

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.



### 11.0 REVIEW AND COMMENTS

# **12.0 ABBREVIATIONS**

S.No.	Abbreviations	Expanded Definition	
1.	PLC	Programmable Logic Controller	
1.	HMI	Human Machine Interface	
2.	I/P	Input	
3.	O/P	Output	
4.	LED	Light Emitting Diode	

### 13.0 APPROVAL SHEET FROM "PCHPL"

The Approver confirms that the Operational Qualification stands completed successfully and that the defined machine is handed over for production

Department	Name	Designation	Sign	Date