OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR AUTOMATIC CAPSULE FILLING MACHINE

EQUIPMENT ID. No.	
LOCATION	**Capsule Filling**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

CONTENTS

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL FOR AUTOMATIC CAPSULE FILLING MACHINE	PROTOCOL No.:

1.0 PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANGER (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Automatic Capsule Filling Machine and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Startup & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this operational qualification protocol cum report is limited to qualification of Automatic Capsule Filling Machine **(**Make – anchor mark**)** to be installed in the Capsule filling.
- This Protocol will define the methods and documentation used to perform OQ activity the Automatic Capsule Filling Machine for OQ. Successful completion of this Protocol will verify that Machine meet all acceptance criteria and ready for PQ.

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
Quality Assurance	• Initiation, Approval and Compilation of the OQ Protocol cum Report. • Co-ordination with Production and Engineering to carryout OQ. • Monitoring of Operational Qualification Activity.
Production	• Review, Pre & Post Approval of Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol.
Engineering	• Review, Pre & Post Approval of Protocol cum Report. • Co-ordination, Execution and technical support in Automatic Capsule Filling Machine Operational Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution).

5.0 EQUIPMENT DETAILS:

Equipment Name	Automatic Capsule Filling Machine.
Equipment	
Manufacturer's Name	
Model	PHARMAFILL A120
Supplier's Name	Anchor mark private limited
Location of Installation	Capsule filling

6.0 SYSTEM DESCRIPTION:

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

6.1 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^{th} 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
- 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

6.2 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.

6.3 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

6.4 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.

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.

6.5 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.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- Draft SOP for operating & Cleaning of Automatic capsule filling Machine.
- Draft SOP for Preventive Maintenance of Automatic capsule filling Machine.
- Technical specification of equipment.

7.1.1 Procedure:

- Verify the above mentioned documents for availability, completeness and approval status
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the OQ Protocol cum report.

7.1.2 Acceptance Criteria:

All the documents should be available, complete and approved by respective authorities.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 VERIFICATION OF DOCUMENTS:

The results of any tests should meet the limits and acceptance criteria specified in the test documents. Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)
1.	DQ Protocol Cum Report		
2.	IQ Protocol Cum Report		
3.	Draft SOP for operating & cleaning of Automatic capsule filling machine		
4.	Draft SOP for preventive maintenance of Automatic capsule filling machine		

Checked By
Sign & Date:

Verified By
Sign & Date:

8.1 TEST EQUIPMENT CALIBRATION:

Verify that all critical instruments associated with the system will be in a calibrated state. Review the calibration status for the test equipment to be utilised and record the calibration due dates in the table below. All Equipment/Instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

Equipment/ Instruments Name	Equipment/ Instrument Id	Calibration On	Due On	Observed By Sign & Date

Checked By
Sign & Date:

Verified By
Sign & Date:

8.2 FUNCTIONAL VERIFICATION OF OPERATIONAL AND FUNCTIONALITY CHECKS:

NOTE: Press the manual mode disabled to enable manual mode.

8.2.1 VACUUM PUMP FUNCTIONALITY TEST:

S. No.	Simulation Methodology	Acceptance Criteria	Observation
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	

Checked By **Verified By**
Sign & Date: **Sign & Date:**

8.2.2 MAIN MACHINE BLOWER FUNCTIONALITY TEST

S.No.	Simulation Methodology	Acceptance Criteria	Observation
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	

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Sign & Date: **Sign & Date:**

8.2.3 ECSE MACHINE FUNCTIONALITY TEST

S. No.	Simulation Methodology	Acceptance Criteria	Observation
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	

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Sign & Date: **Sign & Date:**

8.2.4 MACHINE INCH FUNCTIONALITY TEST

S. No.	Simulation Methodology	Acceptance Criteria	Observation
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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8.2.5 STIRRER MOTOR FUNCTIONALITY TEST

S. No.	Simulation Methodology	Acceptance Criteria	Observation
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	

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Sign & Date: **Sign & Date:**

8.2.6 LOADER -1 FUNCTIONALITY TEST

S. No.	Simulation Methodology	Acceptance Criteria	Observation
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	

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Sign & Date: **Sign & Date:**

8.2.7 LOADER -2 FUNCTIONALITY TEST

S. No.	Simulation Methodology	Acceptance Criteria	Observation
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	

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Sign & Date: **Sign & Date:**

8.2.8 VIBRATOR- 1 INCH FUNCTIONALITY TEST

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

S. No.	Simulation Methodology	Acceptance Criteria	Observation
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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Sign & Date: **Sign & Date:**

8.2.9 VIBRATOR- 2 INCH FUNCTIONALITY TEST

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

S. No.	Simulation Methodology	Acceptance Criteria	Observation
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	

Checked By **Verified By**
Sign & Date: **Sign & Date:**

8.2.10 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
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	

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8.2.11 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
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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8.2.12 MAIN MACHINE (AUTO MODE) FUNCTIONALITY TEST

Note: - All interlocks should be OK

S.No.	Simulation Methodology	Acceptance Criteria	Observation
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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Sign & Date: **Sign & Date:**

8.2.13 SAMPLING SCREEN

S.No.	Simulation Methodology	Acceptance Criteria	Observation
1.	Select Manual mode of sampling after filling data press on TAKE SAMPLE	Fill the following data • Require Segment Sample • Manual Sampling Segment Number • Number of Segments to be Sampled • Delay Time for Next Segment Sample Capsule samples will be collected of the respective segment number	

S.No.	Simulation Methodology	Acceptance Criteria	Observation
1.	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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Verified By
Sign & Date:

8.3 FUNCTIONAL VERIFICATION OF SAFETY INTERLOCK CHECKS

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

Test	Acceptance Criteria		Observation
	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	

Test	Acceptance Criteria		Observation
	Alarm/ Messages	Effect on function	
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:			
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.	

Test	Acceptance Criteria		Observation
	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	
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	

 PHARMA DEVILS	**OPERATIONAL QUALIFICATION PROTOCOL FOR AUTOMATIC CAPSULE FILLING MACHINE**	**PROTOCOL No.:**

Test	**Acceptance Criteria**		**Observation**
	Alarm/ Messages	**Effect on function**	
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	
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	

Test	Acceptance Criteria		Observation
	Alarm/ Messages	Effect on function	
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 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	
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	

Checked By
Sign & Date:

Verified By
Sign & Date:

8.4 POWER FAILURE AND RESTORATION TEST:

S. No.	Procedure	Acceptance Criteria	Observation
1.	• Start the machine in its standard starting procedure. • Trip the main incoming power supply, thereby simulating for Pseudo Power Failure. • Wait for some time and Switch ON the main incoming power supply	• The machine should not start until and unless it is started manually. • No Data should be erased.	

Checked By
Sign & Date:

Verified By
Sign & Date:

Inference:

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Reviewed By
Sign & Date:

9.0 REFERENCES:

The Principle Reference is the following:

- Validation Master Plan
- Schedule-M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2 – Good Manufacturing Practices and Inspection.

10.0 DOCUMENTS TO BE ATTACHED:

- Copy Of Draft SOP's
- Any Other Relevant Documents

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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12.0 CHANGE CONTROL, IF ANY:

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13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

PVT.	:	Private limited
LTD.	:	Limited
IQ.	:	Installation Qualification
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
^{o}C	:	Temperature
RH	:	Relative Humidity
LPM	:	Liter per minutes
Kg.	:	Kilo gram

cGMP	:	Current Good Manufacturing Practice
OQ	:	Operational Qualification
Ltd.	:	Limited
S.S.	:	Stainless Steel
ID.	:	Identification
Kg	:	Kilo gram
Ltrs	:	Liters
mm	:	Millimeter
MCB	:	Miniature circuit break

17.0 POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANGER (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			