OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MIX MANUFACTURING PLANT

EQUIPMENT ID. No.	
LOCATION	**Manufacturing Line**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

PROTOCOL CONTENTS

1.0 PROTOCOL PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

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 Multi-mix manufacturing plant 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, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this Operational Qualification Protocol Cum Report is limited to perform operational qualification of Multi-mix manufacturing plant (Make: Bectochem Consultants & Engineers Pvt. Ltd.) installed in Manufacturing line.
- This Protocol Cum Report will define the methods and documentation used to perform OQ activity of Multi-mix manufacturing plant.
- Successful completion of this Protocol Cum Report will verify that equipment meets all acceptance criteria and ready for Performance Qualification.

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	• Preparation, Review, and Approval of the operational Qualification Protocol Cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification activity. • To compile all the data generated during operational qualification activity. • Monitoring of Operation Process • Post Approval of Operational Qualification Protocol cum Report after Execution.
Production	• Review of Operational Qualification Protocol cum Report. • To execute the operational qualification activity in co-ordination with QA and Engineering. • To provide necessary material (if any) during the operational qualification activity.
Engineering	• Pre-approval of Operational Qualification Protocol cum Report. • To co-ordinate and support Operational Qualification Activity. • To provide necessary utilities required during operation of equipment. • Post Approval review of Operational Qualification Protocol cum Report after Execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	Multi-mix Manufacturing Plant		
ID. Number	…….		
Capacity	**Type of vessel**	**Working Capacity**	**Gross Capacity**
	Wax Phase Vessel	30 Liters	40 Liters
	Water Phase Vessel	30 Liters	40 Liters
	Main Manufacturing Vessel	60 Liters	75 Liters
	Storage Vessel	60 Liters	75 Liters
Manufacturer's Name	Bectochem Consultants & Engineers Pvt. Ltd.		
Supplier's Name	Bectochem Consultants & Engineers Pvt. Ltd.		
Location of Installation	Manufacturing Line		

Checked By
Engineering
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……..

6.0 EQUIPEMENT DESCRIPTION:

The Multi Mix Manufacturing Plant is designed to process pharmaceutical products i.e. Multi mix / cream / gels / lotion in accordance with cGMP principles. The Multi mix manufacturing plant is comprises with following equipments;

1. Wax (Oil) phase Vessel
2. Water (Aqueous) Phase Vessel
3. Main Manufacturing and Mixing Vessel
4. Vacuum Pump (Water Ring Type)
5. Twin Lobe Transfer Pump
6. Storage Tank
7. Product Pipeline
8. Centralized Electric Control Panel for entire process plant
9. In-Line Homogenizer

Wax (Oil) phase Vessel:

It is fitted with bottom mounted stirrer coupled to SS 316 shaft with agitator, pressure gauge, vent valve, safety valve rupture disc, and a temperature sensor with digital display. It is provided with bottom outlet connected to manufacturing vessel through a conical filter having SS mesh screen of 100# filter of melted waxes. It is also provided with the steam supply to the jacket.

Main Manufacturing and Mixing Vessel:

It consists of cylindrical shell and jacketed vessel. It is fitted with the top mounted SS 316 shaft with anchor having baffles and Teflon scrappers moving in a clockwise direction. One more baffles system is mounted in the inner side of the vessel. The vessel is provided with pressure release vent, safety valve rupture disc, gauge and a temperature sensor with digital display. The vessel is provided with bottom homogenizer and unloading of finished product to storage vessel using lobe pump. The vessel is also provided with steam and cooling water to the jacketed tank. The vessel is also provided with light glass, sight glass, charge hole and hand hold on top dished end. High speed homogenizer is installed at the manufacturing vessel.

Utility system:

A utility pendant is provided to bring the utility lines from the service floor to the platform so as to run the utility line below the platform.

7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

Prior to start operational qualification activity, verify the below mentioned documents for their availability and record the same as per below table. Any deviations or issues if observed should be rectified and documented prior to OQ commencing.

S.No.	DOCUMENT NAME	AVAILABLE/NOT AVAILABLE	VERIFIED BY (QA) SIGN/DATE
1.	Executed and approved Design Qualification protocol cum report		
2.	Executed and approved Installation Qualification protocol cum report		
3.	Draft SOP for Operation & Cleaning of manufacturing vessel		
4.	Draft SOP for Preventive Maintenance of manufacturing vessel		

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

7.2 Test / Measuring Equipment Calibration:

Prior to start operational qualification activity, verify the calibration status of instruments of multi-mix manufacturing plant as per below table. Any deviations or issues if observed should be rectified and documented prior to OQ commencing.

S.No.	INSTRUMENT NAME	INSTRUMENT I.D.	CALIBRATION DONE DATE	CALIBRATION DUE DATE	OBSERVED BY SIGN/DATE

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……..

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Manager QA
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8.0 CRITICAL VARIABLES TO BE MET:

8.1 OPERATIONAL AND FUNCTIONAL CHECKS:

8.1.1 WAX (OIL) PHASE VESSEL:

S.No.	TEST	METHOD OF TESTING	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (PRODUCTION) (SIGN/DATE)
1.	Main Power Supply	Connect the main power supply to the master panel of the machine. Turn ON the M.C.B switch available in control panel. Then switch ON the main switch.	Indicators of R-Phase, Y-Phase and B-Phase should glow.		
		Switch ON the PLC/HMI MCB switch	Display with company name		
		Switch ON the MCB-6	Wax phase vessel VFD should get activated		
2.	Agitator speed control	Set the agitator RPM to Minimum_____, Optimum_____, & Maximum_____ through HMI. Measure the agitator RPM with the help of Tachometer	The difference in between set RPM and observed RPM should be greater or less than 5 %.	Minimum RPM_____ Optimum RPM_____ Maximum RPM_____	
3.	Temperature control	Set the process temperature at three different set points and check the functioning of Solenoid valve operation.	Once the temperature reaches to set temperature, the solenoid valve at jacket inlet closes.	SET Temperature: _____ Valve Open/Close:_____ SET Temperature: _____ Valve Open/Close:_____ SET Temperature: _____ Valve Open/Close:_____	
4.	Process Timer	Set 3 different times in control panel and verify the Start / Stop operation of Anchor	The anchor agitator operation start / stop time should match	SET Time : _____ Real time: Paddle Agitator Start	

S.No.	TEST	METHOD OF TESTING	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (PRODUCTION) (SIGN/DATE)
		Agitator against the stop watch in real time.	with time measured with stop watch.	Time:_____ AM/PM Paddle Agitator Stop Time:_____ AM/PM Actual run Time: _____ Min	
5.	Functioning of motor and actuated valve	Set the RPM_____ of agitator and process time_____. Turn "ON" the actuated valve at jacket inlet to attain settable temperature.	After set process time is over, motor will be OFF and actuated valve will be closed.		
6.	HMI Operation	Check the operation of the HMI screen on various parameters.	All the keys should operate as per specification. Screen pad should be readable		

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Manager QA
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8.1.2 WATER PHASE VESSEL:

S.No.	TEST	METHOD OF TESTING	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (PRODUCTION) (SIGN/DATE)
1.	Water phase vessel: Main Power	Switch ON the MCB-5	Water phase vessel VFD should get activated		
2.	Agitator speed control	Set the agitator RPM to Minimum_____, Optimum_____, & Maximum_____ Measure the agitator RPM with the help of Tachometer	The difference in between set RPM and observed RPM should be greater or less than 5 %.	Minimum RPM_____ Optimum RPM_____ Maximum RPM_____	
3.	Temperature control	Set the process temperature at three different set points and check the functioning of Solenoid valve operation.	Once the temperature reaches to set temperature, the solenoid valve at jacket inlet closes.	SET Temperature: ____ Valve Open/Close:_____ SET Temperature: ____ Valve Open/Close:_____ SET Temperature: ____ Valve Open/Close:_____	
4.	Process Timer	Set 3 different times in control panel and verify the Start / Stop operation of Anchor Agitator against the stop watch in real time.	The anchor agitator operation start / stop time should match with time measured with stop watch.	SET Time : _____ Real time: Paddle Agitator Start Time:_____ AM/PM Paddle Agitator Stop Time:_____ AM/PM Actual run Time: _____ Min	

S.No.	TEST	METHOD OF TESTING	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (PRODUCTION) (SIGN/DATE)
5.	Functioning of motor and actuated valve	Set the RPM_____ of agitator and process time_____. Turn "ON" the actuated valve at jacket inlet to attain settable temperature.	After set process time is over, motor will be OFF and actuated valve will be closed.		
6.	HMI Operation	Check the operation of the HMI screen on various parameters.	All the keys should operate as per specification. Screen pad should be readable		

Checked By
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Reviewed By
Manager QA
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8.1.3 MAIN MIXER:

S.No.	TEST	METHOD OF TESTING	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (PRODUCTION) (SIGN/DATE)
1.	Main Mixer: Main Power	Switch ON the MCB	Main Mixer VFD should get activated		
2.	ON/ OFF of the Anchor	Switch ON the Anchor	Agitator should get started		
		Switch OFF the Anchor	Agitator should get stopped		
3.	ON/ OFF of the cowl	Switch ON the cowl	Cowl should get started		
		Switch OFF the cowl	Cowl should get stopped		
4.	ON/ OFF of the Homogenizer	Switch ON the anchor of homogenizer	Homogenizer should get started		
		Switch OFF the anchor of homogenizer	Homogenizer should get stopped		
5.	Emergency stop	Run the mixer and press the emergency stop in between the process	The machine should get stopped immediately		

S.No.	TEST	METHOD OF TESTING	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (PRODUCTION) (SIGN/DATE)
6.	Agitator speed control	Set the Anchor RPM to Minimum_____, Optimum_____, & Maximum_____ Measure the RPM with the help of Tachometer	The difference in between set RPM and observed RPM should be within ± 2 RPM	Minimum RPM_____ Optimum RPM_____ Maximum RPM_____	
		Set the Cowl RPM to Minimum_____, Optimum_____, & Maximum_____ Measure the RPM with the help of Tachometer	The difference in between set RPM and observed RPM should be within ± 2 RPM	Minimum RPM_____ Optimum RPM_____ Maximum RPM_____	
		Set the Homogenizer RPM to Minimum_____, Optimum_____, & Maximum_____ Measure the RPM with the help of Tachometer	The difference in between set RPM and observed RPM should be within ± 2 RPM	Minimum RPM_____ Optimum RPM_____ Maximum RPM_____	
7.	Temperature control	Set the process temperature at three different set points and check the functioning of Solenoid valve operation.	Once the temperature reaches to set temperature, the solenoid valve at jacket inlet closes.	SET Temperature: ____ Valve Open/Close:_____ SET Temperature: ____ Valve Open/Close:_____ SET Temperature: ____ Valve Open/Close:_____	
8.	Process	Set 3 different times in	The anchor		

S.No.	TEST	METHOD OF TESTING	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (PRODUCTION) (SIGN/DATE)
	Timer	control panel and verify the Start / Stop operation of Anchor Agitator against the stop watch in real time.	agitator operation start / stop time should match with time measured with stop watch.	SET Time : _____ Real time: Anchor Agitator Start Time:_____ AM/PM Anchor Agitator Stop Time:_____ AM/PM Actual run Time: _____ Min	
9.	Lifting / Lowering Operation	Lift the bowl by pressing UP button when all the agitator operations are on stop.	The top lid should go up and reach the topmost limit and then stops.		
		Press the Down button when all the agitator operations are on stop.	The top lid should come down touching the bottom limit and stops		
10.	Functioning of motor and actuated valve	Set the RPM_____ of agitator and process time_____. Turn “ON” the actuated valve at jacket inlet to attain settable temperature.	After set process time is over, motor will be OFF and actuated valve will be closed.		
11.	HMI Operation	Check the operation of the HMI screen on various parameters.	All the keys should operate as per specification. Screen pad should be		

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MIX MANUFACTURING PLANT	PROTOCOL No.:

S.No.	TEST	METHOD OF TESTING	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (PRODUCTION) (SIGN/DATE)
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Reviewed By
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8.2 EQUIPMENT VOLUMETRIC CAPACITY (IN LITERS) TEST:

Wax (Oil) Phase Vessel			**Working Capacity:** 40 Liters
Objective	The objective of this test is to demonstrate that Vessel Capacity provided is as agreed with the Equipment supplier and meeting User Requirement.		
Equipment / Instrument Used	Process Water: Calibrated Vessel / equipment to measure required quantity for charging water.		
Method Applied	Charge 40 liters of Process Water using calibrated cylinder/ vessel. Witness the quantity of Water received by the vessel without overflowing. Operate the equipment at process parameters as per SOP on operation & cleaning of manufacturing vessel. Three consecutive trials must be tested as described before, in order to demonstrate Consistent performance.		
Acceptance Criteria	The water should be filled without any overflow in vessel and equipment should operate without any abnormality.		
Observation	**Trial-I**	**Trial-II**	**Trial-III**
Complies / Does not complies			

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PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MIX MANUFACTURING PLANT	PROTOCOL No.:

Water Phase Vessel			**Working Capacity:** 40 Liters
Objective	The objective of this test is to demonstrate that Vessel Capacity provided is as agreed with the Equipment supplier and meeting User Requirement.		
Equipment / Instrument Used	Process Water: Calibrated Vessel / equipment to measure required quantity for charging water.		
Method Applied	Charge 40 liters of Process Water using calibrated cylinder/ vessel. Witness the quantity of Water received by the vessel without overflowing. Operate the equipment at process parameters as per SOP. Three consecutive trials must be tested as described before, in order to demonstrate Consistent performance.		
Acceptance Criteria	The water should be filled without any overflow in vessel and equipment should operate without any abnormality.		
Observation	**Trial-I**	**Trial-II**	**Trial-III**
Complies / Does not complies			

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PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MIX MANUFACTURING PLANT	PROTOCOL No.:

Main Manufacturing Vessel			**Working Capacity:** 60 Liters
Objective	The objective of this test is to demonstrate that Vessel Capacity provided is as agreed with the Equipment supplier and meeting User Requirement.		
Equipment / Instrument Used	Process Water: Calibrated Vessel / equipment to measure required quantity for charging water.		
Method Applied	Charge 60 liters of Process Water using calibrated cylinder/ vessel. Witness the quantity of Water received by the vessel without overflowing. Operate the equipment at process parameters as per SOP on operation & cleaning of manufacturing vessel. Three consecutive trials must be tested as described before, in order to demonstrate Consistent performance.		
Acceptance Criteria	The water should be filled without any overflow in vessel and equipment should operate without any abnormality.		
Observation	**Trial-I**	**Trial-II**	**Trial-III**
Complies / Does not complies			

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Manager QA
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8.3 JACKET PRESSURE TEST

Objective	The objective of this test is to check the pressure of the jacket.							
Procedure	• Close the outlet and drain nozzles of jacket. Fill the jacket with water. • Close all nozzles to jacket (Inlet). Pressurize jacket using the pump to desired pressure i.e. 4.5 kg/cm^2 for main manufacturing vessel, 6.0 kg/cm^2 for water phase vessel and wax phase vessel. • Monitor the pressure developed using calibrated Pressure Gauge. • Monitor the pressure for half an hour with time interval of every 10 minutes and check the pressure drop in the gauge. • Any discrepancies to be noted on the review form and on the Deviation Report. *Note: The hydro test pressure is equal to 1.5 times the design pressure as mentioned in GA drawing (Design pressure for main manufacturing vessel is 3.0 kg/cm^2 , Water phase vessel and wax phase vessel is 4.0 kg/cm^2.*							
Acceptance Criteria	No pressure drop should be observed for 30 Minutes.							
Observation	**Main Mixing Vessel**			**Water Phase Vessel**			**Wax Phase Vessel**		
	Time	**Pressure as shown on gauge**	**Pressure Drop**	**Time**	**Pressure as shown on gauge**	**Pressure Drop**	**Time**	**Pressure as shown on gauge**	**Pressure Drop**
Complies / Does not complies									

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MIX MANUFACTURING PLANT	PROTOCOL No.:

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Manager QA
Sign/Date: ……

8.4 VACUUM TEST

Objective	The objective of this test is to perform the vacuum test.
Procedure	• Close the RCVD nozzle and lid. • Vacuumed the tank. Mark the vacuum developed on the Calibrated Vacuum gauge once it has achieved the steady state. • Shut the valve and Check for the drop if any over a period of half an hour. Record the values in the table below every 10 minutes. Any discrepancies to be noted on the Deviation Report.
Acceptance Criteria	No Vacuum drop should be observed for 30 Minutes.

Observation

Main Mixing Vessel			Water Phase Vessel			Wax Phase Vessel		
Time	**Vacuum as shown on gauge**	**Vacuum Drop**	**Time**	**Vacuum as shown on gauge**	**Vacuum Drop**	**Time**	**Vacuum as shown on gauge**	**Vacuum Drop**

Complies / Does not complies			

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Manager QA
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8.5 LOAD TRIAL FOR MIXER

Objective	To verify Performance of agitator on full load mixer.
Procedure	• Fill the vessels with water as per their working capacity & then turn the main supply ON, press start button. • Operate agitator for one hour. • Monitor the current drawn by motor, Sound, Vibration, overheating of the components and document in observation table.
Acceptance Criteria	• The ampere reading should not exceed the rated Amp of motor. • Sound must not exceed 80 dB at 1 meters linear distance. • Temperature shall be recorded for information.

Observation

Main Mixing Vessel

Description	Noise Level	Temperature	Current (Rated Current: 2.5 Ampere)			RPM
			R	Y	B	
Motor						
Gearbox						
Bearing Housing						
Mechanical Seal						

Homogenizer

Description	Noise Level	Temperature	Current (Rated Current: 3.1 Ampere)			RPM
			R	Y	B	
Motor						

Water Phase Vessel

Description	Noise Level	Temperature	Current (Rated Current: 1.1 Ampere)			RPM
			R	Y	B	
Motor						

Wax Phase Vessel

Description	Noise Level	Temperature	Current (Rated Current: 1.1 Ampere)			RPM
			R	Y	B	
Motor						

Complies / Does not complies	

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MIX MANUFACTURING PLANT	PROTOCOL No.:

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Production
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Sign/Date: ……

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Reviewed By
Manager QA
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8.6 INTERLOCK AND ALARM VERIFICATION

S.No.	TEST	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
1.	Interlock of anchor motor with Lid position	The anchor motor should not start if lid is open		
2.	Emergency stop fault	The plant should get stopped on pressing the emergency press.		
3.	Anchor motor FB fault	The anchor motor FB fault alarm should be displayed as specified		
4.	Anchor motor trip	The Anchor motor trip alarm should be displayed as specified		
5.	Water phase motor FB fault	The water phase motor FB fault alarm should be displayed as specified		
6.	Water phase motor trip	The Water phase motor trip alarm should be displayed as specified		
7.	Power pack motor FB fault	The power pack motor FB fault alarm should be displayed as specified		
8.	Power pack motor trip	The power pack motor trip alarm should be displayed as specified		
9.	Vacuum pump FB fault	The vacuum pump FB fault alarm should be displayed as specified		
10.	Vacuum pump trip	The Vacuum pump trip alarm should be displayed as specified		
11.	Homogenizer motor FB fault	The Homogenizer motor FB fault alarm should be displayed as specified		
12.	Homogenizer motor trip	The Homogenizer motor trip alarm should be displayed as specified		
13.	Lobe pump FB fault	The Lobe pump FB fault alarm should be displayed as specified		
14.	Lobe Pump trip	The Lobe Pump trip alarm should be displayed as specified		
15.	Metering pump FB fault	The Metering pump FB fault alarm should be displayed as specified		

S.No.	TEST	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
16.	Metering pump trip	The Metering pump trip alarm should be displayed as specified		
17.	Mechanical seal flow switch FB fault	The Mechanical seal flow switch FB fault alarm should be displayed as specified		
18.	Vacuum flow switch FB fault	The Vacuum flow switch FB fault alarm should be displayed as specified		
19.	MMT top disk open fault	The MMT top disk open fault alarm should be displayed as specified		
20.	Wax phase vessel product temperature high	The Wax phase vessel product temperature high alarm should be displayed as specified		
21.	Water phase vessel product temperature high	The Water phase vessel product temperature high alarm should be displayed as specified		
22.	Vacuum not release fault	The Vacuum not release fault alarm should be displayed as specified		
23.	Air pressure fault	The Air pressure fault alarm should be displayed as specified		
24.	MMT load capacity overloaded	The MMT load capacity overloaded alarm should be displayed as specified		

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Sign/Date: …….

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Manager QA
Sign/Date: …….

8.7 USER ACCESS / RIGHTS VERIFICATION

Mode		Level 1 (Operator)		Level 2 (Supervisor)		Level 3 (Manager)	
		As specified	Actual	As specified	Actual	As specified	Actual
Auto		√		√		√	
Maintenance		X		X		√	
Manual		√		√		√	
Data Entry	Edit	√		√		√	
	Load	√		√		√	
	Change Password	X		X		√	
Date & Time entry		X		X		√	
Complies / Does not complies							
Observed by (Production) (Sign. / Date)							

√ – Authorized

X – Not authorized

Checked By
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Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

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Reviewed By
Manager QA
Sign/Date: ……

8.8 SECURITY LEVEL VERIFICATION (PASSWORD PROTECTION)

User Level	Method of Verification	Acceptance Criteria	Observation	Complies / Does not complies	Observed By (Sign. / Date)
Level 1 (Operator)	Login with correct user name and password	The system should be accessible			
	Login with incorrect user name and password	The system should not be accessible			
Level 2 (Supervisor)	Login with correct user name and password	The system should be accessible			
	Login with incorrect user name and password	The system should not be accessible			
Level 3 (Manager)	Login with correct user name and password	The system should be accessible			
	Login with incorrect user name and password	The system should not be accessible			

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Production
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Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

8.9 POWER FAILURE VERIFICATION:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions. Press Again Login and cycle restart.		

Checked By
Production
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Verified By
Quality Assurance
Sign/Date: ……....

Inference:

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Reviewed By
Manager QA
Sign/Date: …….

9.0 REFERENCES:

- 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:

- Draft Standard operating procedures.
- Any other Relevant Documents.

11.0 DEVIATION FROM PREDEFINED 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:

°C	:	Degree centigrade
%	:	Percentage
cGMP	:	Current Good Manufacturing Practices
SS	:	Stainless Steel
ID.	:	Identification
Sign	:	Signature
LTD.	:	Limited
HMI	:	Human Machine Interface
M.C.B.	:	Miniature Circuit Breaker
No.	:	Number
OQ	:	Operational Qualification
QA	:	Quality Assurance
RPM	:	Rotation per Minute
SOP	:	Standard operating procedure
WHO	:	World Health Organization

17.0 PROTOCOL POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			