OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR MULTI-MIX MANUFACTURING PLANT MANUFACTURING LINE

EQUIPMENT/INSTRUMENT ID No.	
LOCATION	**MANUFACTURING LINE**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PROTOCOL CONTENTS

1.0 PRE -APPROVAL

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER / EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
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 demonstrate that the system will operate reproducibly and consistently within its operating range.
- 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 friendly point of view of the Machine, Cleaning Procedure, and Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The Protocol covers all aspects of Operation Qualification for Multi Mix Manufacturing plant.
- This Protocol will define the methods and documentation used to qualify the Multi Mix Manufacturing plant for OQ. Successful completion of this Protocol will verify that the Multi Mix manufacturing plant meet all acceptance criteria and is 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.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Approval and Compilation of the Operation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operation Qualification. • Monitoring of Operation Process.
Production	• Review of Operation Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operation Qualification study as per Protocol. • Post Approval of Operation Qualification Protocol after Execution
Engineering	• Review of Operation Qualification. • To co-ordinate and support Operation Qualification Activity. • Calibration of Process Instruments.

5.0 EQUIPMENT DETAILS:

Equipment Name	Multi Mix Manufacturing plant
Equipment ID No.	
Manufacturer's Name	Propack Technologies Pvt. Ltd.
Supplier's Name	Propack Technologies Pvt. Ltd.
Model	MP 250
Capacity	250 kg
Location of Installation	Manufacturing Line

6.0 SYSTEM DESCRIPTION:

The Multi Mix Plant with load cell and its associated equipment are designed to process pharmaceutical products in accordance with cGMP principles.

The Multi Mix Plant with load cell is used to Heat/Cool, Mix & Stir Water Phase & Wax Phase by using Bottom Stirrer. A Bottom Stirrer is controlled by VFD. A stirrer is engaged to check continuous homogenized mixing of element when in cycle of duty. Steam is provided for heating. A layer of mineral glass wool wrapped around control the heat loss into atmosphere due to dissipation of the heat. Multi Mix Plant contain temperature sensor for sensing the inside temperature.

The temperature is set through the control panel. Steam is passed through the steam inlet and the desired temperature is achieved. The wax phase vessel contains a Drain through which the condensed steam will come out in form of water. A pressure gauge/p safety valve is also provided on jacket, so that the steam pressure does not exceed the set value, for safety. The stirrer motor of 1 HP is mounted on the stand which is made of SS 304. Mixing is start – (by means of push button provided at control panel) stirrer which will run with a help of a motor Check whether wax is ready for mixing. The wax is transferred by means of Vacuum by opening the outlet valve to the main manufacturing vessel through conical filter.

7.0 PRE-QUALIFICATION REQUIREMENTS:

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.

7.1 System Pre-requisites:

S.No.	Description	Completed (Yes/No)	Checked by Production Sign & Date	Verified by QA Sign & Date
1.	Verify that the DQ/IQ of the Multi Mix Manufacturing plant has been executed and approved. DQ Protocol Cum Report No. ……			
2.	IQ Protocol Cum Report No.: ……			
1.	Verify that the draft operating and Cleaning SOPs has been prepared and available. Draft Operation and cleaning SOP No.:			

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Production
Sign & Date…….

Verified By
Quality Assurance
Sign & Date…….

Inference:……

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Reviewed By
Manager QA
Sign & Date:……

8.0 CRITICAL VARIABLE TO BE MET:

8.1 OPEARATIONAL AND FUNCTIONAL CHECKS:

Operate the Multi Mix Plant as per Manufacturer's Manual / SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

ACTIVITY	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN & DATE)
Water Phase Vessel:			
Open the Purified Water valve	Water is charged in the vessel until valve is open		
Press the **water on** push button for Agitator Rotation	Water on button shall glow in Green. The motor shall start and agitator shall rotate in Clockwise Direction		
Press the **water off** push button for Agitator Rotation	Water off button shall glow in red. The motor shall stop.		
Wax Phase Vessel:			
Press the **Wax on** push button for Agitator Rotation	Wax on button shall glow in Green. The Motor shall start and Agitator shall rotate in Clockwise Direction		
Press the **wax off** push button for agitator rotation	Wax off button shall glow in Red. The motor shall Stop		
Manufacturing Vessel:			
Press the Green **'HSE ON'** button for Homogenizer	Homogenizer shall Start		
Press the Green **'HSE OFF'** Button for Homogenizer	Homogenizer shall Stop		

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Sign & Date:……

8.2 OPERATIONAL QUALIFICATION TEST:

8.2.1 Equipment Volumetric Capacity (In Liters) Test:

8.2.1.1 Objective:

- The purpose of this test is to demonstrate that Vessel Capacity provided is as agreed with the Equipment supplier and meeting User Requirement (300 ltr. total volume and 250 kg Working Volume of manufacturing vessel / 200 liter total volume and 150 liter working volume of water and wax phase vessel).

8.2.1.2 Equipment / Instrument Used:

- Process Water: Calibrated Vessel/ QC equipment to measure required quantity for charging Water for Injection.

8.2.1.3 Method Applied:

- Charge 300 / 150 / 150 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.

DATE OF TEST	VOLUME OF TANK	TEST PERFORMED	ACCEPTANCE CRITERIA	OBSERVATION
	***250 kg.**		*251.8 to 248.2	
	***150 Ltr.**		*151.05 to 148.95	
	***150 Ltr.**		*151.05 to 148.95	

Note: (*) on the basis of the density of water the capacity in liters consider as kg.

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Reviewed By:_____
Manager QA
Sign & Date

8.2.2 VERIFICATION OF SPRAY BALL :

8.2.2.1 Objective:

To demonstrate the spray ball of vessel is capable of removing the traces of 1 % of riboflavin & 0.2 % of Mannitol solution from the vessel surface & to check the working of spray ball during running trial.

8.2.2.2 Material:

Water, Riboflavin, Mannitol

8.2.2.3 UTILITIES:

Pump, Hosepipe, U.V. Light, painting brush

Pressure gauge

8.2.2.4 Method:

- Prepare 1 % of riboflavin & 0.2 % of Mannitol solution in one bucket.
- Apply riboflavin solution uniformly on the vessel & nozzle through spray ball.
- Allow the vessel to dry about 10-20 minute
- Open the vessel outlet valve & operate the pump with water @ 1-2 bar pressure for 30 minute at the flow rate of 73 LPM. And that time stirrer should be on position
- Observe the tank visually under U.V. Light
- Adequate precaution shall be taken during observation
- The area where having significant residue of riboflavin , it will glow prominently under the U.V. illumination

DATE OF TEST	ACCEPTANCE CRITERIA	OBSERVATION
	Spray pattern of water found all over 360° uniformly & all the surface of vessel internal should be free from riboflavin	

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8.2.3 THREE LEVEL PASSWORD VERIFICATION:

8.2.3.1 Objective:

To demonstrate that the three level password capable to deliver the desired output to start the process.

8.2.3.2 Method:

- Switch on the main control panel.
- Select the user ID such as Admin, Akums, supervisor and Operator.
- Enter the password.
- Process Details shall be display on HMI.
- Select the Data and Start the Process.

8.2.3.3 Acceptance Criteria:

Authorized Person should be operating the machine as per provided rights and if password wrong then machine should not operate.

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Reviewed By:_____
Manager QA
Sign & Date

8.3 SAFETY TESTING / INTERLOCKING:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN & DATE)
Electrical Wiring and Earthing	Must be inside the machine		
Motor Overload Relay	The switchgear shall trip if overloaded		
Emergency Off	Machine should stop immediately		
Safety Valve	To Release Excess Pressure		

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Sign & Date:……

8.4 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.		

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Quality Assurance
Sign & Date…….

Inference:……

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Reviewed By
Manager QA
Sign & Date:……

8.5 EMERGENCY OPERATION VERIFICATION:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN & DATE)
Emergency Stop			
• Press Emergency Stop Push Button.	Equipment should Stop.		
• Release Emergency Stop Push Button. •	Equipment should Start.		
With the Emergency Stop Pressed in, try to cause movement of an Operating function.	The Equipment will be Inoperative.		

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Production
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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:

- 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:

WHO	:	World Health Organization
MMP	:	Multi mix manufacturing plant
IQ	:	Installation Qualification
Pvt.	:	Private
Ltd.	:	Limited
MOC	:	Material of construction
QA	:	Quality Assurance
Vol.	:	Volume
MCB	:	Miniature Circuit Breaker
cGMP	:	Current Good Manufacturing Practice
Qty.	:	Quantity
Dia.	:	Diameter
HP	:	Horse Power
RPM	:	Revolution per minute
V	:	Volt
^{o}C	:	Degree Celsius
PU	:	Poly Urethane
SS	:	Stainless steel
NMT	:	Not more than
RH	:	Relative Humidity
Temp.	:	Temperature
DQ	:	Design Qualification
VFD	:	Variable Frequency drive

17.0 POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER / EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			