OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MIX PLANT

EQUIPMENT ID No.	
LOCATION	**Manufacturing Line**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**Nil**

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

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 with load cell 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 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
Manufacturer's Name	Propack Technologies Pvt. Ltd.
Supplier's Name	Propack Technologies Pvt. Ltd.
Model	
Capacity	500 kg
Location of Installation	Manufacturing Area
Equipment ID No.	

6.0 SYSTEM DESCRIPTION:

To design and manufacture multi mix plant for processing of ointment / cream / gels / lotion as per product safety, cGMP guideline and to provide assurance that the equipment is manufactured as per the URS and it complies with the scope of supply.

1. Multi mixer manufacturing vessel
2. Wax phase vessel
3. Water phase vessel
4. Transfer pump
5. Electric control panel
6. Vacuum pump
7. Utility system
8. Batch storage vessel working platform
9. Homogenizer
10. Meter in pump

Multi Mixer manufacturing 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. It is a silverson type homogenizer and consists of slit sleeve type SS 316 blade and rotates at 2800 RPM.

Wax 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.

Water 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.

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.

There is a manual mode of operation for manufacturing plant-500 kg. For manual mode selector switches are provided on control panel to control the parameter.

- Water inlet : 1" dia. TC flanged end.
- Water outlet : 1" dia. TC flanged end.
- Cooling water inlet : 1" dia. TC flanged end.
- Cooling water outlet : 1" dia. TC flanged end.

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 OF PRE-REQUISITE	COMPLETED (YES/NO)	CHECKED BY PRODUCTION SIGN & DATE	VERIFIED BY QA SIGN & DATE
1.	Verify that the DQ/IQ of the Multi Mix Plant has been executed and approved. DQ Protocol Document No.:			
2.	IQ Protocol Document No.:			
3.	Verify that the draft operating and Cleaning SOPs has been prepared and available.			

8.0 CRITICAL VARIABLE TO BE MET:

8.1 OPEARATIONAL AND FUNCTIONAL CHECKS:

Operate the manufacturing 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 Stirrer 1 ON'** push button for stirrer	Water on button shall glow in Green. The motor shall start and shall rotate in Clockwise Direction		
Press the '**Water Stirrer 1 OFF'** push button for stirrer	Water off button shall glow in red. The motor shall stop.		
Wax Phase Vessel:			
Press the '**Wax Stirrer 1 ON'** push button for stirrer	The Motor shall start and shall rotate in Clockwise Direction.		
Press the '**Wax Stirrer 1 OFF'** push button for stirrer	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		
Press the green 'B PUMP ON' button.	Bump Pump shall start.		
Set the speed on the VFD on panel & press Run.	Agitator shall move.		

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

ACTIVITY	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN & DATE)
Press 'STOP' on VFD	Agitator shall Stop..		
Switch on 'V PUMP' switch on the panel.	Vacuum pump shall start.		
Switch off 'V PUMP' switch on the panel.	Vacuum pump shall stop.		

Checked By_____
Production
Sign & Date

Verified By_____
Quality Assurance
Sign & Date

Inference:……..

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Reviewed By:_____
Manager QA
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 (750 liters total volume and 600 liters Working Volume of manufacturing vessel / 420 liter. Total volume and 350 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 600 / 350 / 350 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
	***600 Ltr.**		*601.8 to 598.2	
	***350 Ltr.**		*351.05 to 348.95	
	***350 Ltr.**		*351.05 to 348.95	

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

Checked By_____
Production
Sign & Date

Verified By_____
Quality Assurance
Sign & Date

Inference:……..

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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

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 valve.
- 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 and that time stirrer should be on position
- Observe the tank visually under light
- Adequate precaution shall be taken during observation
- The area where having significant residue of riboflavin, it will glow prominently under light.

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	

Checked By_____
Production
Sign & Date

Verified By_____
Quality Assurance
Sign & Date

Inference:……..

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Reviewed By:_____
Manager QA
Sign & Date

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.

Checked By_____
Production
Sign & Date

Verified By_____
Quality Assurance
Sign & Date

Inference:……..

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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		

Checked By_____
Production
Sign & Date

Verified By_____
Quality Assurance
Sign & Date

Inference:……..

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Reviewed By:_____
Manager QA
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.		

Checked By_____
Production
Sign & Date

Verified By_____
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.		

Checked By_____
Production
Sign & Date

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:

- 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 ABBREVATION:

OQ	:	Operational Qualification
MMP	:	Multi Mix Plant
WHO	:	World Health organization
QA	:	Quality Assurance
Vol.	:	Volume
SOP	:	Standard operating procedure
DQ	:	Design Qualification
IQ	:	Installation Qualification
Dia.	:	Diameter
Kg.	:	Kilogram
SS	:	Stainless steel
RPM	:	Revolution per minute
cGMP	:	Current Good manufacturing Practice
Pvt.	:	Private
Ltd.	:	Limited

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)			