



**INSTALLATION QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
MULTI MIX MANUFACTURING PLANT**

**PROTOCOL No.:**

**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
MULTI MIX PLANT**

<b>EQUIPMENT ID NO.</b>	
<b>LOCATION</b>	<b>Manufacturing Line</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES PROTOCOL NO.</b>	<b>NIL</b>



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**1.0 PRE -APPROVAL :**

**INITIATED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>HEAD (PRODUCTION)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>HEAD (QUALITY ASSURANCE)</b>			



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**2.0 OBJECTIVE:**

- To carry out the Installation Qualification of **Multi-Mix Plant** with **Model MP 500** procured **Propack Technologies Pvt. Ltd.** to be used for Manufacturing of Creams/Gel & Multi mix.
- To confirm that the equipment and its components are as per the Specifications and Installed as per the approved Design and complies with cGMP practices.
- To prove that each Operation proceeds as per the Design Specification and the tolerances prescribed there in the document, are the same at utmost transparency.
- To ensure that there is sufficient information available to enable the equipment to be operated and maintained safely, effectively and consistently.

**3.0 SCOPE:**

- To verify the critical dimensions of the unit and record Serial Numbers/Model number of critical components.
- To verify that the correct hardware has been installed, system initializes correctly.
- To record the as-built drawing numbers of equipment drawing, P & ID and circuit diagram.
- To Calibrate Temperature and Pressure measurements of Control System, Recorder, Gauges and displays.



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**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.

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review, Approval and Compilation of the Installation Qualification Protocol cum Report.</li><li>• Co-ordination with Production and Engineering to carryout Installation Qualification.</li><li>• Monitoring of Installation Qualification Activity.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review of Protocol cum Report.</li><li>• Execution of Installation Qualification.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review of Protocol cum Report.</li><li>• To co-ordinate and support Installation Qualification Activity.</li><li>• Calibration of Process Instruments.</li></ul>

**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Multi-Mix Manufacturing Plant
<b>Equipment ID</b>	
<b>Manufacturer's Name</b>	Propack Technologies Pvt. Ltd.
<b>Supplier's Name</b>	Propack Technologies Pvt. Ltd.
<b>Model</b>	MP 500
<b>Location of Installation</b>	Manufacturing Line



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**6.0 SYSTEM DESCRIPTION:**

To design and manufacture multi mix plant for processing of Multi mix/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. Transfer pump
4. Electric control panel
5. Vacuum pump
6. Utility system
7. Batch storage vessel working platform
8. Homogenizer
9. Meter in jump

**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.



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**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-400 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 IQ 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 of the Multi-Mix Plant has been executed and approved. DQ Protocol Document No.:			



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**8.0 CRITICAL VARIABLE TO BE MET:**

**8.1 GENERAL CHECKS AND LOCATION SUITABILITY:**

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN & DATE)
Grouting and Mounting of Equipment	Eng. / Production / QA to Certify		
Equipment should be Properly Balanced & Leveled			
All The Metal Parts Should Be Properly Grounded Without any Sharp Edges.			
Welding of Joints Without Any Welding Burrs			
Place of Installation	Manufacturing Line		
Room Condition	Temp NMT 25 <sup>0</sup> C RH NMT 55%		
Illumination	NLT 300 Lux.		
Working space around the Equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		

**Checked By** \_\_\_\_\_  
**Production**  
**Sign & Date**

**Verified By** \_\_\_\_\_  
**Quality Assurance**  
**Sign & Date**

**Inference:**.....  
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**Reviewed By:** \_\_\_\_\_  
**Manager QA**  
**Sign & Date**





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**8.2 INSTALLATION CHECKS VERIFICATION:**

S.No.	TEST PARAMETER	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING SIGN & DATE
<b>A. Multi Mixing manufacturing vessel:</b>				
1.	Check any physical damage to multi mix vessel.	There should no damage to the mixing vessel		
2.	Check specification of multi mixing vessel.	Working capacity: 625 lt. Gross capacity: 750 lt. Min. Batch size: 200 lt. Shell thickness: 6 mm cyl. Insulation : 2 mm Thk. Legs : SS 304 3 Nos. Jacket thickness: 5 mm Bottom thickness: 7 mm conical. Inside finish : mirror finish Outside finish : matt finish		
3.	Check the specification of agitator motor	5 HP / internal agitator / 415 V / 1440 RPM FLP Make: Hindustan		
4.	Check the specification of gear Box	GEAR BOX, TYPE- W, GEAR BOX SIZE -110, REDUCTION RATIO -20:1, FRAME TYPE-112, MOUNTING TYPE-U MAKE :BONIFIGLIOLI		
5.	Check the specification of product sensor	Make: radix Type : PT – 100 MOC: SS 316 L End connection : 1/2” BSP Temperature range (0 – 200)		
6.	Check the specification of product outlet valve	Make : Cipriani Ø38mm dia., SS 316 L outlet Pneumatic operated radial diaphragm valve		



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S.No.	TEST PARAMETER	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING SIGN & DATE
7.	Check the specification of water Inlet.	make : Inoxpa Size : 25 mm dia. With pneumatic operated butterfly valve		
8.	Check the specification of CIP.	make : Inoxpa Size : 40 mm dia. With pneumatic operated butterfly valve MOC : SS 316 L		
9.	Check the specification of ingredient suction valve.	make : Inoxpa Size : 25 mm dia. TC Type : Flexible hose & pneumatic operated butterfly valve		
10.	Check the specification of vent filter valve	make : Inoxpa Size : 25 mm dia. TC end Type : pneumatic operated butterfly valve		
11.	Check the specification of safety valve.	make : Inoxpa Size : 25 mm dia. TC		
12.	Check the specification of pressure gauge	Make : Baumer MOC: SS 304 Range: 0- 10 kg/cm <sup>2</sup> End conn-1/4" BSP Dial Size : 2.5"		
13.	Check the specification of compound gauge	Make : Baumer MOC: SS 316 L Range: 760mmHg to 10 kg/cm <sup>2</sup> End conn-3/8" BSP Dial Size : 4"		
14.	Check the specification of recirculation	make : Inoxpa Size : 38 mm dia. TC end Type : pneumatic operated divert valve		
15.	Check the specification of wax inlet	make : Inoxpa Size : 25 mm dia. TC end Type : pneumatic operated butterfly valve		



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16.	Check the specification of Spray ball	Make : Atul Ø50mm dia., End conn-3/4" BSP SS 316 L		
17.	Check the specification of additive hopper	make : Inoxpa Size : 38 mm dia. TC end Type : manual butterfly valve		
18.	Steam inlet / cooling outlet	Size : 25 mm TC with pneumatic		
19.	Steam outlet / cooling inlet	Size : 25 mm TC with pneumatic piston valve Make : Spirex		

**B. Wax Phase vessel**

1.	Check any physical damage to Wax phase vessel.	There should no damage to the mixing vessel		
2.	Check specification of wax phase vessel.	Working capacity: 350 lt. Gross capacity: 420 lt. Min. batch size: 105 lt. Shell thickness: 5 mm Vessel top : 2 mm thick SS 316 L with flat top 1/3 openable Insulation : 2 mm thick Legs: made of SS 304 – 04 Nos. Jacket thickness : 4 mm Vessel inside finish : mirror finish Outside finish : matt finish		
3.	Check the specification of motor	Top entry saw cutter type Make : Hindustan 2 HP 960 RPM / 415 V FLP		



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S.No.	TEST PARAMETER	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING SIGN & DATE
4.	Check the specification of product temperature sensor	Make: radix Type : PT – 100 MOC: SS 316 L End connection : 1/2” BSP Temperature range (0 – 200)		
5.	Check the specification of product outlet valve	Make : Cipriani Size : 25 mm Type : Pneumatic operated redial diaphragm valve		
6.	Check the specification of safety valve.	make : Inoxpa Size : 25 mm dia. TC		
7.	Check the specification of air vent on jacket	Size : 25 mm dia. TC end		
8.	Check the specification of hot steam inlet	25 mm TC with pneumatic operated piston		
9.	Check the specification of hot steam outlet	25 mm TC with pneumatic operated piston valve Make: Spirex		
10.	Check the specification of Spray ball	Make : Atul End conn-3/4” BSP SS 316 L		
11.	Check the specification of pressure gauge	Make : Baumer MOC: SS 304 Range: 0- 10 kg/cm <sup>2</sup> End conn-1/4” BSP		

**C. Water phase heating vessel**

1.	Check any physical damage to water phase heating vessel.	There should no damage to the water phase vessel		
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2.	Check specification of multi mixing vessel.	Working capacity: 350 lt. Gross capacity: 420 lt. Min. batch size: 105 lt. Shell thickness: 5 mm Vessel top : 2 mm thick SS 316 L with flat top 1/3 open able Insulation : 2 mm thick Legs: made of SS 304 – 04 Nos. Jacket thickness : 4 mm Vessel inside finish : mirror finish Outside finish : matt finish		
3.	Check the specification of motor	Top entry marine type impeller Make : Hindustan 2 HP 960 RPM / 415 V FLP		
4.	Check the specification of product sensor	Make: radix Type : PT – 100 MOC: SS 316 L End connection : 1/2" BSP Temperature range (0 – 200)		
5.	Check the specification of product outlet valve	Make : Cipriani Size : 25 mm bottom valve Type : Pneumatic operated redial diaphragm valve		
6.	Check the specification of CIP.	make : Inoxpa Size : 50 / 25 mm With pneumatic operated butterfly valve		
7.	Check the specification of safety valve.	make : Inoxpa Size : 25 mm dia. TC		
8.	Check the specification of air vent on jacket	Size : 25 mm dia. TC end		
9.	Check the	Make : Atul		



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S.No.	TEST PARAMETER	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING SIGN & DATE
	specification of Spray ball	End conn-3/4" BSP SS 316 L		
10.	Check the specification of hot steam inlet	25 mm TC with pneumatic operated piston valve Make: Spirex		
11.	Check the specification of hot steam outlet	25 mm TC with pneumatic operated piston valve Make: Spirex		
12.	Check the specification of pressure gauge	Make : Baumer MOC: SS 304 Range: 0- 10 kg/cm <sup>2</sup> End conn-1/4" BSP		
13.	Air vent	Size : 25 mm TC end MOC : 304		

**D. Working Storage vessel**

1.	Check any physical damage to working storage vessel.	There should no damage to the working storage vessel.		
2.	Check specification of multi mixing vessel.	Working capacity: 600 lt. Gross capacity: 690 lt. Min. batch size: 180 lt. Shell thickness: 2 mm flat Legs: made of SS 304 – 04 Nos. Vessel inside finish : mirror finish Outside finish : matt finish		
3.	Check the specification of CIP.	make : Inoxpa Size : 50 / 25 mm With pneumatic operated butterfly valve		
4.	Check the specification of product outlet valve	Make : Cipriani Size : 40 mm TC end bottom valve Type : Pneumatic operated redial diaphragm valve		
5.	Check the	Make : Cipriani		



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S.No.	TEST PARAMETER	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING SIGN & DATE
	specification of product inlet valve	Size : 40 mm TC end Type : Pneumatic operated butterfly valve		
6.	Check the specification of Spray ball	Make : Atul End conn-3/4" BSP SS 316 L		
<b>E. Transfer Pump (Lobe Pump)</b>				
1.	Check any physical damage to transfer Pump	There should no damage to the transfer pump		
2.	Check specification of Transfer Pump	Type : Twin Lobe MOC: SS 316 L Inlet / outlet-25 mm TC Motor : 2.0 HP / 415V / 760 RPM Make : Hindustan		
<b>F. Electrical Control panel</b>				
1.	Check any physical damage to electrical control panel	There should no damage to the electrical control panel		
2.	Check specification of Transfer Pump	Make : PTPL		
<b>G. Vacuum Pump</b>				
1.	Check any physical damage to Vacuum Pump	There should no damage to the Vacuum Pump		
2.	Check specification of Transfer Pump	Type : Water Ring Size : 3 HP / 415V / 2800 RPM Make : Hindustan 1015M566260		
<b>H. Working Platform</b>				
1.	Check any	There should no damage to the		



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S.No.	TEST PARAMETER	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING SIGN & DATE
	physical damage to Working platform	working platform		
2.	Check specification of Transfer Pump	Size : 4000 X 1000 X 1000 mm MOC : SS3 304		
<b>I. Meter In Pump</b>				
1.	Check any physical damage to meter in pump	There should no damage to the meter in pump		
2.	Check specification of meter in pump	Type :Reciprocating Plunger Type , volume adjustable Motor : 1.0 HP / 415V / 1440 RPM Make : Hindustan Size : 25 mm TC 1015M56504		
<b>J. Homogenizer</b>				
1.	Check any physical damage to Homogenizer	There should no damage to the Homogenizer		
2.	Check specification of meter in pump	Motor : 1.0 HP 2800/ RPM / 440V Mounting- bottom of the vessel in conical portion Make : Hindustan 1015M56504		
3.	VFD	VFD , POWER – 10hp , 50Hz FLP Voltage : AC 3 phase Make Siemens		





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Quality Assurance  
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**8.3 UTILITIES REQUIRED:**

PARAMETERS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING SIGN & DATE
Electricity	3 Phase Plus Earthing, 5 Wire Line Up To The Panel Board Terminal. Voltage- <b>440 ± 10% V -18.5 HP</b> Frequency- <b>50 ± 3% Hz</b>		
Steam	Shall be properly connected and Identified		
Cooling Water	Shall be properly connected and Identified		
Compressed Air	6.0 kg/cm <sup>2</sup>		
Vacuum	6-8 bar		

**8.4 MATERIAL OF CONSTRUCTION:**

S.No.	COMPONENTS	MOC	OBSERVATION	OBSERVED BY ENGINEERING SIGN & DATE
1.	All contact Parts	AISI SS 316		
2.	Shell	AISI SS 316		
3.	Bottom	AISI SS 316		
4.	Top	SS 316		
5.	Flange	AISI SS 316L		
6.	Gaskets	Food Grade		
7.	Jacket	SS 304		
8.	Legs	SS 304		
9.	Insulation	Fiber Wool (Mineral Wool) Asbestos Free		



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S.No.	COMPONENTS	MOC	OBSERVATION	OBSERVED BY ENGINEERING SIGN & DATE
10.	Transfer Pump ( LOBE PUMP )	SS316 (Product Contact Parts)		
11.	Meter-in Pump	SS 316 (Product Contact Part)		
12.	<b>Working Platform:</b> <ul style="list-style-type: none"> <li>• Square Pipe Frame Work with Top SS</li> <li>• Dimple Sheet Ladder</li> <li>• Railing is provided on all three sides of the Platform.</li> <li>• Legs (Round Pipe Legs are provided)</li> <li>• Platform (GMP Standard Paint Free)</li> </ul>	SS 304		
13.	<b>Batch Storage Vessel:</b> <ul style="list-style-type: none"> <li>• Shell 16 SWG (Cylindrical type)</li> <li>• Bottom 16 SWG (Conical type welded with shell)</li> <li>• Top 16 (Loose type Lid)</li> <li>• Legs with PU Castor wheel with Bracket</li> </ul>	SS 316 (All Contact Parts)  SS 304		

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**8.5 INSTALLATION CHECKS:**

<b>S.No.</b>	<b>SPECIFICATION</b>	<b>OBSERVATION</b>	<b>OBSERVED BY (ENGINEERING) (SIGN &amp; DATE)</b>
1.	Verify that major components are protected from shock and there is no physical damage		
2.	Check the proper mechanical installation of multi mix plant		
3.	Check the proper electrical installation of multi mix plant		
4.	Verify that all piping and electrical connection have been done according to the drawings		
5.	Verify that the required electrical connections are tight, weather proofed and grounded.		
6.	Equipment identification nameplate is visible		
7.	Unit are installed on foundation and secured in place as per manufacturer recommendations		
8.	All access ports are examined and cleared of any debris.		
9.	Wiring diagram is glued or taped to inside section of control panel		
10.	Verify that there is sufficient room for servicing provided		
11.	Check the equipment is free from any defects		
12.	Check the finishing of product contact parts		
13.	Verify that the 'As Built' Drawings		



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<b>S.No.</b>	<b>SPECIFICATION</b>	<b>OBSERVATION</b>	<b>OBSERVED BY (ENGINEERING) (SIGN &amp; DATE)</b>
	are Complete and represent the design concept		
<b>14.</b>	There should not be any loose fasteners		
<b>15.</b>	There should not be any loose electrical connection		
<b>16.</b>	There should not be any damage		

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**8.6 SAFETY:**

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING (SIGN & DATE)
Pressure Switches	For product safety and Gasket safety		
Electrical wiring and Earthing	Electrical wiring should be as per approved drawings. Double external earthing to control machine (panel and motors) and operator should be provided.		
Motor overload relay – The switchgear shall trip if overloaded	Should be provided For Motor safety		
<b>Emergency off:</b> To stop the process immediately	Should be provided For equipment and operator safety		
<b>Safety clamps:</b> For holding product container and acting as a jumper for earth continuity of PC and RC	For equipment and product safety		
MCB	MCB is provided so that when there is an overload in current or any short circuit then the MCB trips.		
Mechanical Guard	Mechanical guard for all rotating parts.		
Joints	Welding of joints without any welding burrs		
Metal Parts	All the metal parts should be		



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	properly grounded without any sharp Edges.		
Leveling And Balancing	Equipment should be properly Balanced & Leveled		
Cooling arrangement	Cooling arrangement provided for motor shaft and seal with special flow switch to detect water, so only if cooling water is circulated then only homogenizer will operate, this ensures long life of the equipment.		
Operating Panel	Is provided on platform of the Equipment for operator safety.		
Dimple sheet	Platform to ensure proper grip during walking and railing is provided as safety feature.		

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**8.7 Spare parts:** List of spare parts to be attached (if any)

**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:**

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC
- Calibration certificates

**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 ABBREVIATION:**

- WHO : World health organization
- MOC : Material of Construction
- MCB : Miniature circuit Breaker
- SS : Stainless Steel
- PU : Poly urethane
- SWG : Slandered Wire gauge
- cGMP : Current Good Manufacturing Practice
- HP : Horse power
- Hz : Hertz
- VFD : Variable frequency Drive
- RPM : Revolution per minute
- FLP : Flame proof
- V : Volt
- PTPL : Propack Technologies private limited
- CIP : Cleaning in place
- RH : Relative Humidity
- MMP : Multi mix manufacturing plant
- P & ID : Piping and Instrumentation diagram



**INSTALLATION QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
MULTI MIX MANUFACTURING PLANT**

**PROTOCOL No.:**

**17.0 POST APPROVAL**

**INITIATED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

**REVIEWED BY:**

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

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			