



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

**PROTOCOL No.:**

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

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</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 manufacturing Plant (250 Kg)** with **Model MP 250** procured **Propack Technologies Pvt. Ltd.** to be used for Manufacturing of Creams / Gel & Cosmetic.
- 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.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<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>
Production	<ul style="list-style-type: none"><li>• Review of Protocol cum Report.</li><li>• Execution of Installation Qualification.</li></ul>
Engineering	<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:**

Equipment Name	Multi mix manufacturing Plant
Manufacturer's Name	Propack Technologies Pvt. Ltd.
Supplier's Name	Propack Technologies Pvt. Ltd.
Capacity	250 kg
Model	MP 250
Location of Installation	Manufacturing line



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**6.0 SYSTEM DESCRIPTION:**

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 IQ commencing.

**7.1 System Pre-requisites:**

S.No.	Description of pre-requisite	Completed (Yes/No)	Checked by Engineering 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	Equipment should be grouted and mounted		
Balancing and Leveling of equipment	Equipment should be properly balanced and leveled		
Metal Parts	All The Metal Parts Should Be Properly Grounded Without Any Sharp Edges.		
Welding of joints	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  
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Sign & Date.....**

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Quality Assurance  
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**Reviewed By:\_\_\_\_\_**  
**Manager QA**  
**Sign & Date**



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**8.2 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	650 to 760 mm. /Hg		

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**8.3 MATERIAL OF CONSTRUCTION:**

S.No.	Components	MOC	Observation	Observed By Engineering Sign & Date
1.	All contact Parts	SS 316		
2.	Shell	SS 316		
3.	Bottom	SS 316		
4.	Top	SS 316		
5.	Flange	SS 316L		
6.	Gaskets	Food Grade		
7.	Jacket	SS 304		
8.	Legs	SS 304		
9.	Insulation	Fiber Wool (Mineral Wool Asbestos Free)		
10.	Transfer Pump ( LOBE PUMP )	SS316 (Product Contact Parts)		
11.	Meter-in Pump	SS 316 (Product Contact Part)		
	<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		
12.	<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> </ul>	SS 316 (All Contact Parts)  SS 304		

S.No.	Components	MOC	Observation	Observed By Engineering Sign & Date
	<ul style="list-style-type: none"> <li>Legs with PU Castor wheel with Bracket</li> </ul>			

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**8.4 EQUIPMENT VERIFICATION:**

Parameters	Acceptance criteria	Observation	Observed By Engineering Sign & Date
<b>Equipment</b>	Multi-Mix manufacturing Plant		
<b>Model No.</b>	MP 250		
<b>Capacity</b>	250 Kg		
<b>Overall Dimension</b>	<b>Height</b> : 1900 mm (Approx) <b>Width</b> : 2500 mm (Approx) <b>Length</b> : 5600 mm (Approx)		
<b>(1) Manufacturing Vessel</b>	<b>Qty</b> : 1 Nos.		
	<b>Capacity</b> : 250 kg		
	<b>Light Glass</b> : 4" Dia. with Lamp		
	<b>Sight glass</b> : 6" Dia toughen glass.		
	<b>Extra Connection</b> : 1" Dia TC 1 Nos.		
	<b>Ingredient Suction</b> : 1" Dia TC with flexible hose & Butterfly valve		
	<b>Spray ball</b> : 1" Dia. TC 2 Nos. for spray ball.		
	<b>Stirrer</b> : Mounted on centre of the dish		
<b>(a) Vessel Connection on side of the top shell</b>	<b>Wax Inlet</b> : 1" Dia with TC Union		
	<b>Water Inlet</b> : 1" Dia with TC Union.		
	<b>Recirculation</b> : 1 ½" Dia with TC Union		
<b>(b) Vessel Connection on bottom of the top shell</b>	<b>Outlet</b> : 1 ½" Dia. flush bottom valve with TC Union.		
	<b>Product Sensor</b> : PT- 100 with temperature indicator.		
	<b>Homogenizer</b> : On conical portion		
<b>(c) Vessel Design</b>	<b>Temperature</b> : 150°C		
	<b>Pressure</b> : 2 kg/cm <sup>2</sup>		



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Parameters	Acceptance criteria	Observation	Observed By Engineering Sign & Date
	<b>Vacuum:</b> 650-760 mm/hg.		
<b>(d) Jacket Connection</b>	<b>Steam Inlet:</b> 1" Dia. TC Flanged End		
	<b>Cooling Outlet:</b> 1 ½" Dia. TC or Flanged End		
	<b>Cooling Inlet:</b> 1 ½" Dia. TC or Flanged End		
	<b>Steam Condensate:</b> 1" Dia. TC or Flanged End		
	<b>Drain:</b> 1 ½" Dia. TC or Flanged End		
	<b>Connection for:</b> Safety valve, Pressure gauge & Air vent is provided		
<b>(e) Jacket Design</b>	<b>Temperature:</b> 150°C		
	<b>Pressure:</b> 4 kg/cm <sup>2</sup> working & 6 kg/cm <sup>2</sup> Hydraulic Test		
<b>(f) Agitator</b>	<b>Type:</b> Teflon Scrappers Floating Type.		
	<b>Speed:</b> Frequency controller is provided for vary speed.5 to 48 RPM.		
	<b>Speed Regulation:</b> Variable frequency drive provided for speed variation. (Delta)		
	<b>Shaft Seal:</b> Dry Mechanical Seal		
	<b>Motor:</b> 3 HP / 440 V/1500 RPM		
	<b>Gear Box:</b> Size-W-110. Ratio-30:1		
<b>(g) Homogenizer</b>	<b>Type:</b> Bottom of the vessel in conical portion.		
	<b>Shaft Seal:</b> Double cartridge mechanical seal with TC seal. Face with cooling water arrangement for the mechanical seal and an electronic water detection sensor to trip the motor if the flow of water to the mechanical seal is stopped,		
	<b>Motor:</b> 7.5 HP /2800 RPM/440V.		



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Parameters	Acceptance criteria	Observation	Observed By Engineering Sign & Date
	<b>Safety:</b> safety of mechanical seal flow switch is provided.		
	<b>Weld and Finish details:</b> Vessel will be argon arc welded.		
	<b>Internally:</b> 0.5 Ra 210 grit (Mirror polish)		
	<b>Externally:</b> 180 grit (Matt polish)		
	Vessel is 0 to -760 mm. /hg Vacuum Tight		
<b>(2) Wax Phase Vessel</b>	<b>Capacity :</b> 150 Liters		
	<b>Shell:</b> 4mm Thick, Cylindrical type.		
	<b>Bottom:</b> 4mm Thick, Dish Type welded with shell.		
	<b>Top:</b> 16 SWG thick, loose with 1/3rd Open able type.		
	<b>Flange:</b> 12 mm thick		
	<b>Jacket:</b> 4 mm thick , spiral type stiffeners for uniform heating and cooling		
	<b>“0” Ring:</b> Silicon food grad.		
	<b>Legs:</b> legs 3 nos.		
	<b>Cladding:</b> made of 14 SWG welded type.		
	<b>Inline Conical Filter:</b> 100 Made of SS 316 L , mesh (for filtration of WAX Phase)		
<b>(a) Vessel Connection on Top LID</b>	<b>Stirrer :</b> Mounted on centre of the Lid		
<b>(b) Vessel Connection on bottom of the Vessel</b>	<b>Outlet:</b> 1” Dia. flush bottom valve with TC fittings.		
	<b>Product Sensor:</b> P.T. 100 with temperature indicator.		
<b>(c) Vessel Design</b>	<b>Temperature:</b> 150°C		
	<b>Pressure:</b> 2 kg/cm <sup>2</sup>		
<b>(d) Jacket Connection</b>	<b>Steam Inlet:</b> 1” Dia. TC or Flanged End		



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Parameters	Acceptance criteria	Observation	Observed By Engineering Sign & Date
	<b>Steam Condensate:</b> 1" Dia. TC or Flanged End		
	<b>Drain:</b> 1 ½" Dia. TC or Flanged End		
	<b>Connection for:</b> Safety valve, Pressure gauge & Air vent is provided		
<b>(e) Jacket Design</b>	<b>Temperature:</b> 150° C		
	<b>Pressure:</b> 4 kg/cm <sup>2</sup> working & 6 kg/cm <sup>2</sup> Hydraulic Test		
<b>(f) Agitator:</b>	<b>Type:</b> Saw Cutter type		
	<b>Motor:</b> 1 HP / 440 V/ 960 RPM.		
	<b>Weld and Finish details:</b> Vessel will be argon arc welded.		
	<b>Internally:</b> 0.5 Ra 210 grit (Mirror polish)		
	<b>Externally:</b> 180 grit (Matt finish)		
<b>(3) Water Phase Vessel</b>	<b>Capacity:</b> 150 Liters.		
	<b>Shell:</b> 4mm Thick, Cylindrical type.		
	<b>Bottom:</b> 4mm Thick, Dish Type welded with shell.		
	<b>Top:</b> 16 SWG thick, Loose with 1/3rd Open able type.		
	<b>Flange:</b> 16 mm thick		
	<b>Jacket:</b> 4 mm thick, Spiral type stiffeners for uniform heating and cooling.		
	<b>"0"Ring:</b> silicon food grade. .		
	<b>Legs:</b> pipe legs (3 Nos.)		
	<b>Cladding:</b> made of 14 SWG welded type.		
<b>Inline Conical Filter:</b> 100mesh (for Filtration of WAX Phase)			
<b>(a) Vessel Connection on Top LID</b>	Stirrer : Mounted on centre of the dish		
<b>(b) Vessel Connection on Bottom of the Vessel</b>	<b>Outlet:</b> 1" Dia. flush bottom valve with common pipe line		



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Parameters	Acceptance criteria	Observation	Observed By Engineering Sign & Date
	fitting		
	<b>Product Sensor:</b> P.T. 100 with temperature indicator.		
<b>(c) Vessel Design</b>	<b>Temperature :</b> 150°C		
	<b>Pressure :</b> 2 kg/cm <sup>2</sup>		
<b>(d) Jacket Connection</b>	<b>Steam Inlet :</b> 1" Dia. TC or Flanged End		
	<b>Steam Condensate:</b> 1" Dia. TC or Flanged End		
	<b>Drain :</b> 1 ½" Dia. TC or Flanged End		
	<b>Connection for :</b> Safety valve, Pressure gauge & Air vent is provided		
<b>(e) Jacket Design</b>	<b>Temperature :</b> 150°C		
	<b>Pressure :</b> 4 kg/cm sq. working & 6 kg/cm sq Hydraulic Test		
<b>(f) Agitator</b>	<b>Type:</b> Propeller type/Saw cutter type		
	<b>Motor:</b> 1 HP / 440 V/ 960 RPM.		
	<b>Weld and Finish Details:</b> Vessel will be argon arc welded.		
	<b>Internally:</b> 0.5 Ra 220 grit (Mirror polish)		
	<b>Externally:</b> 180 grit (Matt finish)		
<b>(g) Interconnecting Pipelines</b>	Pipeline from wax melting vessel to COSMETIC Manufacturing Vessel with conical Filter (100mesh)		
	All pipelines are electro polished and joints are TC fitting for easy dismantling & cleaning		
<b>(4) Transfer Pump (LOBE PUMP )</b>	Rotors are accurately machined and located on sturdy shafts		
	Two mechanical seals are provided on two shafts.		
	Mounted on stand with geared 1.5 HP / 440v / 760 RPM		
	<b>Output:</b> 1800 liters/hr		



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Parameters	Acceptance criteria	Observation	Observed By Engineering Sign & Date
	<b>Inlet size:</b> 1½” Dia. TC		
	<b>Outlet size:</b> 1 ½” Dia. TC		
<b>(5) Vacuum Pump</b>	<b>Type:</b> Water Ring Type		
	3 HP / 440V / 2800 RPM / Water Ring Type		
	<b>Capacity:</b> 760 mm/hg.		
	<b>Water inlet flow required:</b> 6-8 Lit/Min		
	<b>Water Temperature:</b> Ambient		
<b>(a) Utility Required</b>	<b>Soft Water Inlet:</b> 1” Dia. line		
	<b>Chilled water inlet line:</b> 1” Dia. line		
	<b>Chilled water outlet line:</b> 1”dia line.		
	<b>Drain line:</b> 1” Dia. Line		
<b>(6) Meter-in Pump</b>	<b>Type:</b> Reciprocating Plunger type, Volume adjustable.		
	<b>Motor:</b> 0.5 HP / 440V / 1440 RPM		
	Head 2.5 meter		
	<b>Inlet:</b> 1” Dia. line		
	<b>Outlet:</b> 1 ” Dia. line		
<b>(7) Batch Storage Vessel</b>	<b>Qty.:</b> 4 Nos.		
	<b>Working Capacity:</b> 300 Liters		
	<b>Inlet:</b> 1 ½” TC		
	<b>Outlet:</b> 1 ½” Dia. with Butterfly valve		





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**8.5 INSTALLATION CHECKS:**

S.No.	Specification	Observation	Observed By Engineering Sign & Date
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 are Complete and represent the		



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S.No.	Specification	Observation	Observed By Engineering Sign & Date
	design concept		
14.	There should not be any loose fasteners		
15.	There should not be any loose electrical connection		
16.	There should not be any damage		

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**8.6 SAFETY:**

Checks	Acceptance criteria	Observation	Observed by Engineering Sign & Date
Well embedded equipment	For cGMP site layout		
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		



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<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 should be provided for all rotating parts.		
Joints	Welding of joints should be without any welding burrs		
Metal Parts	All the metal parts should be 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.		



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Dimple sheet	Platform to ensure proper grip during walking and railing is provided as safety feature.		

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**Manager QA**  
**Sign & Date**

**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



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**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
°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



PHARMA DEVILS

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

**PROTOCOL No.:**

**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)			