



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

PROTOCOL No.:

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

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



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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)			



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2.0 OBJECTIVE:

- To carry out the Installation Qualification of Multi-Mix manufacturing plant procured from Bectochem Consultants & Engineers 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 ensure that there is sufficient information available to enable the equipment to be operated and maintained safely, effectively and consistently.

3.0 SCOPE:

- The scope of this document is limited to perform installation qualification of Multi-Mix manufacturing plant procured from Bectochem Consultants & Engineers Pvt. Ltd.
- 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 and verify the as-built drawing numbers of equipment drawing, P & ID and circuit diagram.
- To identify the instruments of multi mix manufacturing plant for calibration and to calibrate the same.



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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 cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Preparation, Review and Approval of Installation Qualification Protocol cum Report.• Assist in the verification of installation checks, Drawings, as per the Specification.• Co-ordination with Production and Engineering to carryout installation Qualification.• Monitoring of Installation Qualification activity.• Post Approval of Installation Qualification Protocol cum Report after Execution.
Production	<ul style="list-style-type: none">• Review of Installation Qualification Protocol cum Report.• Assist in the verification of installation checks, Drawings, as per the Specification.• Review of installation qualification protocol cum report after execution.
Engineering	<ul style="list-style-type: none">• Review of Installation Qualification Protocol cum Report.• To execute the installation qualification activity.• To verify installation checks, Drawings, as per the Specification i.e.<ul style="list-style-type: none">• Specification of the sub-components / bought out items, their Make, Model, Quantity and Backup Records / Brochures.• Details of Utilities• Material of Construction of all components• Brief Equipment Description• Safety Features and Alarms• Review of installation qualification protocol cum report after execution.



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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		



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6.0 SYSTEM 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.



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7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document
- Verification of Certificate of material of construction of components.
- Verification of Calibration Certificate of test Instrument.

7.1.1 Procedure:

- Verify the above mentioned documents for availability and completeness.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum report.

7.1.2 Acceptance Criteria:

All the documents should be available, complete and approved by respective authorities.



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8.0 CRITICAL VARIABLES 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 ⁰ C RH NMT 55%		
Illumination	NLT 300 Lux.		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		
Electrical connections	Should be provided & secured		
Earthing Connection to control panel & equipment	Earthing connection to control panel & equipment should be provided.		

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:

8.2 Utility Verification:

PARAMETER	ACCEPTANCE CRITERIA		OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN & DATE)
Electricity	Voltage	415 ± 10 % V		
	Phases	3 Phase		
	Frequency	50 Hz		
Steam	Shall be properly connected and identified			

Remark: Check the voltage / frequency with the help of Multimeter / Clamp meter on supply cable. Attach calibration certificate of Multimeter / Clamp meter with report.

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8.3 Documentation Verification

Following documents shall be verified for their availability.

S.No.	DOCUMENT	DOCUMENT No. (IF APPLICABLE)	OBSERVED BY (ENGINEERING) (SIGN & DATE)
1.	Approved Design qualification protocol cum report		
2.	Drawings		
3.	MOC Certificates		
4.	Purchase Order		

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8.4 Installation Checks:

S.No.	SPECIFICATION	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
1.	Verify that the “As built” drawings are complete and represent the design concept.		
2.	Check the proper mechanical installation of multi-mix manufacturing plant.		
3.	Check the proper electrical installation of multi-mix manufacturing plant.		
4.	Check the equipment is free from any defects.		
5.	Check the finishing of product contact parts.		
6.	Verify that major components are securely anchored and protected from shock.		
7.	Verify that there is no observable physical damage.		
8.	Verify that “Room layout” drawing is OK and sufficient space for servicing is provided.		

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Quality Assurance
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Inference:

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Manager QA
Sign/Date:



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8.5 Verification of Technical Specification:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
1. Wax (Oil) Phase Vessel			
Gross Capacity	40 Liters		
Working Capacity	30 Liters		
Maximum Operating Pressure	Vessel – Atmospheric, Jacket: 3.5 Kg / cm ²		
Design Pressure	Vessel – Atmospheric, Jacket: 4.5 Kg / cm ²		
Hydro-Test Pressure	Vessel – Water Fill up, Jacket: 4.0 Kg / cm ²		
Operating Temperature	Vessel – 100 °C, Jacket: 120 °C		
Design Temperature	Vessel – 120 °C, Jacket: 150 °C		
Joint Efficiency (Shell / Disc)	0.7		
Shell	350 mm ID x 400 mm HT x 3 THK		
Top	400 mm ID, Loose lid 16 SWG		
Bottom	30° Cone x 3 THK		
Jacket	30° Cone x 3 THK		
Jacket Shell	425 mm ID x 300 mm HT x 3 THK		
Insulation	50 THK, Mineral Wool		
Cladding	16 SWG SS304		
Surface finish of contact parts	Mirror finish, 240 grit level		
Surface finish of non-contact parts	Matt finish, 180 grit level		
Agitator marine propeller hollow type	RPM: Maximum 960		
	MOC: SS316		
	Motor: 05 HP, Non FLP, Single speed hollow shaft motor, Sweep Dia. of marine propeller 130 mm		
	Mounting: Entire assembly mounting on G bracket to mount inclined agitator		
Exposed Threaded Fasteners	No threads exposed, Dome bolts are used.		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Crevices / corners	No crevices. Rounded corners smooth surfaces.		
Cleaning requirements	Parts easily assessable for cleaning. Vessel Body is washable.		
Gasket	Food grade Silicon gaskets used in Sealing valves which are non-shredding, process compatible washable and easily accessed.		
Product Temperature Sensor with Transmitter and Thermowell			
Make	Sai Tech.		
Model	PT-100		
MOC	SS316		
Pressure Gauge			
Make	Baumer		
Range	0-10 Kg/ cm ²		
Size	4" Dial, 1/2" BSP		
MOC	SS316 L		
Electrical Power			
Capacity	0.5 HP		
Connection Type / Voltage	415 Volts / 50 Hz		
Steam			
Capacity	6 Kg/ hour		
Connection Type	15 NB (each)		
Water Phase Vessel			
Gross Capacity	40 Liters		
Working Capacity	30 Liters		
Maximum Operating Pressure	Vessel – Atmospheric, Jacket: 3.5 Kg / cm ²		
Design Pressure	Vessel – Atmospheric, Jacket: 4.5 Kg / cm ²		
Hydro-Test Pressure	Vessel – Water Fill up, Jacket: 4.0 Kg / cm ²		
Operating Temperature	Vessel – 100 °C, Jacket: 120 °C		
Design Temperature	Vessel – 120 °C, Jacket: 150 °C		



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Corrosion Allowance	Nil		
Joint Efficiency (Shell / Disc)	0.7		
Shell	350 mm ID x 400 mm HT x 3 THK		
Top	400 mm ID, Loose lid 16 SWG		
Bottom	30° Cone x 3 THK		
Jacket dish	30° Cone x 3 THK		
Jacket Shell	425 mm ID x 300 mm HT x 3 THK		
Insulation	50 THK, Mineral Wool		
Cladding	16 SWG SS304		
Surface finish of contact parts	Mirror finish, 240 grit level		
Surface finish of non-contact parts	Matt finish, 180 grit level		
Agitator marine propeller hollow type	RPM: Maximum 960		
	MOC: SS316		
	Motor: 05 HP, Non FLP, Single speed hollow shaft motor, Sweep Dia. of marine propeller 130 mm		
	Mounting: Entire assembly mounting on G bracket to mount inclined agitator		
Sealing Arrangement	No particles to shred within the Body, all gaskets are of food silicon. Lubricants or coolants and utilities required for operation not in contact with product.		
Exposed Threaded Fasteners	No threads exposed, Dome bolts are used.		
Crevices / corners	No crevices. Rounded corners smooth surfaces.		
Gasket	Food grade Silicon gaskets used in Sealing valves which are non-shredding, process compatible washable and easily accessed.		
Critical Instruments	Correctly calibrated and certified for the intended use.		
Product Temperature Sensor with Transmitter and Thermowell			



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Make	Sai Tech.		
Model	PT-100		
MOC	SS316		
Pressure Gauge			
Make	Baumer		
Range	0-10 Kg/ cm ²		
Size	4" Dial, 1/2" BSP		
MOC	SS316 L		
Electrical Power			
Capacity	0.5 HP		
Connection Type / Voltage	415 Volts / 50 Hz		
Steam			
Capacity	6 Kg/ hour		
Connection Type	15 NB (each)		
2. Main Manufacturing and Vessel			
Gross Capacity	75 Liters		
Working Capacity	60 Liters		
Maximum Operating Pressure	Vessel – Atmospheric, Jacket: 3.5 Kg / cm ²		
Design Pressure	Vessel – Atmospheric, Jacket: 4.5 Kg / cm ²		
Hydro-Test Pressure	Vessel – Water Fill up, Jacket: 4.0 Kg / cm ²		
Operating Temperature	Vessel – 100 °C, Jacket: 120 °C		
Design Temperature	Vessel – 120 °C, Jacket: 150 °C		
Corrosion Allowance	Nil		
Joint Efficiency (Shell / Disc)	0.7		
Product Contact Part	SS316		
Electrical Rating	415 V, 50 Hz, 3 Phase		
Vessel shape	The vessel is vertical cylindrical jacketed and insulated. Mounted on legs		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
	Polished, Ra ≤ 0.8 (equivalent to 240 grit finish)		
	Seal Quality: Food grade silicon		
Jacket	Jacket for heating with spiral stiffener rings which affect better heat transfer. Jacket is designed for hot/cold water. Stiffener provides better strength to the vessel against positive and negative pressure.		
	MOC: SS304		
Insulation and Cladding	MOC: SS304, Material of insulation: Mineral wool		
Anchor Agitator	MOC: SS 316		
	Variable Frequency Drive should be available		
	The shaft should be supported by a bearing house with 2 taper roller bearings back to back		
	Motor: 3 HP, 1440 RPM, Non-flame proof		
	PTFE scrappers should be provided on the anchor. These scrappers should remain in contact with the vessel surface providing 100 % sweep.		
Bottom Valve	65 mm nominal bore		
	SS316		
Sealing Arrangement	All parts should be properly sealed. All sealing gaskets should be of food grade silicon.		
Crevice / Corners	There should not be any crevices. Rounded corners with smooth surfaces provided.		
Gasket	Food grade Silicon gaskets should be used in sealing valves which are non-shredding, process compatible washable and easily accessed.		
Main shell	MOC: SS316 Inner Diameter: 470 mm Thickness: 4 mm Make: BCEPL		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Top Dish	MOC: SS316 Inner Diameter: 470 mm 10 % Std. Torrispherical Dish Make: BCEPL		
Bottom Cone	MOC: SS304 Inner Diameter: 470 mm Thickness: 4 mm Conical Shape Make: BCEPL		
Jacket Shell	MOC: SS304 Inner Diameter: 558 mm Thickness: 3 mm Make: BCEPL		
Jacket Cone	MOC: SS304 Inner Diameter: 558 mm Thickness: 3 mm Conical Shape Make: BCEPL		
Insulation Shell Cladding	MOC: SS304 14" SWG Make: BCEPL		
Insulation Cone Cladding	MOC: SS304 14" SWG Shape: Conical Bottom Make: BCEPL		
Insulation	Thickness: 40 mm MOC: Mineral Wool Make: BCEPL		
Earthing Boss	MOC: SS 304 Qty. 2 Nos. Make: BCEPL		
Agitator Shaft	MOC: SS 316 Make: BCEPL		
Anchor Impeller	MOC: SS316 30 x 6 mm thick plate Make: BCEPL		
Gearbox	Sr. No.: W63 Make Bonfiglioli		
Hydraulic Column	1 HP, 60 Bore x 300 stroke Make: BCEPL		
Jacket Needle Valve	MOC: SS 304, ½" BSP Manually Operated Needle Valve Make: BCEPL		
Jacket Safety Relief Valve	MOC: SS 304, Safety Relief Valve, ½" BSP Make: Darshan		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Jacket Inlet	MOC: SS 304, 15 NB, Manually Operated Ball Valve Make: Jekon		
Jacket Outlet	MOC: SS 304, 15 NB, Pneumatically Operated Ball Valve Make: Jekon		
Product Transfer valves	MOC: SS 316, 1", Pneumatically Actuated Butterfly Valve Make: Jekon		
Vent & Vacuum valves	MOC: SS 316, ½", Manually Operated Ball Valve Make: Jekon		
Vent Filter	MOC: SS 316, mounting stem, 5 Micron, 1" TC Make: Blinex		
Mechanical Seal	Single Cartridge, Dry Mech. Seal Make: Hi-Fab		
Conical Filter	MOC: SS 316 housing, 4" to 1" TC End with 100 Mesh filter Make: BCEPL		
Lobe Pump	MOC: SS 316, 1.0 HP, 1440 RPM, NFLP, 3 Meter Head, SS 304 Trolley Mounted Make: Jakim		
BOTTOM ENTRY HOMOGENIZER	2 HP, 2880 RPM, NFLP, 3 Phase, 415V, 2" TC (both ports) Make: BCEPL		
Metering Pump	MOC: SS 316, 200 Litres per Hour, 1 HP, 1440 RPM, NFLP, Make: Jakim		
Vacuum Pump	1 HP, 3 Phase, 1440 RPM, Non FLP, Water Ring Type Make: Jakim		
3. Storage Vessel			
Gross Capacity	75 Liters		
Working Capacity	60 Liters		
Type	The vessel should be cylindrical, vertical & Non-jacketed top loose lid, conical bottom. Vessel should be supported with SS304 legs		
Shell	450 mm ID x 350 mm HT		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Top	450 mm ID, Loose lid 16 sw		
Bottom	30° Cone		
Steam Control Valves	Solenoid valve ON / OFF type (Pneumatically actuated) Qty. 01 No. Make: AVCON		
Control panel	Push button type, Carbon steel painted, Floor resting, MS powder coated, Non-flame proof		
Display and Control	RPM indicator, Cowl disperser, Temperature indicator cum controller		
RPM	Variable Frequency Drive Make: Mitsubishi for anchor		
Temperature Sensor	Product and Jacket PT 100 sensor		
4. Transfer Pump – Twin lobe type			
Mounting	Should be mounted on trolley with castor wheels, Nylon PU coated		
Capacity (Flow rate)	3000 Liters / hr, Basis: Water		
Head	2.0 Meter		
Pressure	3 Kg / Cm ²		
Suction connection	1 ^{1/2} "		
Discharge connection	1 ^{1/2} "		
MOC, Contact parts	SS316		
Motor	1 HP, 720 RPM		
Mounting	Skid mounted on common SS frame.		
5. Storage Tank			
Gross Capacity	75 Liters		
Working Capacity	50 Liters		
Sealing Arrangement	All parts should be properly sealed. All sealing gaskets should be of food grade silicon.		
Crevices / Corners	There should not be any crevices. Rounded corners with smooth surfaces provided.		



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Gasket	Food grade Silicon gaskets should be used in sealing valves which are non-shredding, process compatible washable and easily accessed.		
Shell	ID - 470 mm, Thickness - 4 mm MOC – SS316 Make – BCEPL		
Top Lid	Flat loose lid with locking arrangement, MOC – SS316 Make – BCEPL		
Bottom Cone	ID - 470 mm, Thickness - 4 mm, Conical bottom, MOC – SS316 Make – BCEPL		
Leg Support	MOC - SS 304 Make – BCEPL		
Product Transfer valves	SS 316L, 1”, Manually Operated Butterfly Valve Make –Jekon		
Nozzle N1	Product Inlet		
Nozzle N3	Tank Outlet		
Electrical Control Panel	<ol style="list-style-type: none"> 1. Main Switch, Electrical digital temperature indicator for all vessel 2. DOL Starter for metering pump 3. Fuses for all motors 4. Indicator lamps for main ON/OFF with selector switch 5. DOL Starter for lobe pump 6. DOL starter for propeller agitators 7. Starter with overload relay for cowl disperser, Homogenizer and Anchor type agitator 8. Potentiometer for speed control of main anchor stirrer, cowl disperser 	Design requirement	
6. High Shear Mixer Emulsifier (Homogenizer)			
Model	OL 02		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Type	Skid mounted with T.C clamp		
Motor Type	2 HP, 2880 RPM, Non-FLP		
Supply Voltage	415 V, 3 Phase, 50 Hz		
Control	ON/OFF		
Suction connection	1.5"		
Discharge connection	1"		

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8.6 MATERIAL OF CONSTRUCTION:

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Wax (Oil) Phase Vessel				
Product Contact Parts				
1.	Vessel Shell	SS316L		
2.	Vessel Top dish	SS316L		
3.	Vessel Bottom cone	SS316L		
4.	Agitator Shaft	SS316L		
5.	Propeller Impeller	SS316L		
6.	Bottom Valve	SS316L		
7.	D.M. WAX Charging Valve	SS316L		
8.	Nozzle N1, N3 Pipe TC	SS316L		
9.	Nozzle N6, Flange	SS316L		
10.	Nozzle N8 Pipe Socket	SS316L		
Product Non-Contact Parts				
11.	Jacket Shell	SS 304		
12.	Jacket cone	SS 304		
13.	Insulation Shell Cladding	SS 304		
14.	Insulation Dish Cladding	SS 304		
15.	Leg Support	SS 304		
16.	Jacket Safety Needle Valve	SS 304		
17.	Jacket Safety Relief Valve	SS 304		
18.	Jacket- Hot water inlet	SS 304		
19.	Jacket- Hot water outlet	SS 304		



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S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
20.	Nozzle N4, Pipe TC	SS304		
21.	Nozzle N5 Pipe Socket	SS304		
Main Mixer Vessel				
Product Contact Parts				
1.	Vessel main shell & bottom dish	SS316L		
2.	Top Dish	SS316L		
3.	Agitator shaft	SS316L		
4.	Anchor impeller	SS316L		
5.	Jacket safety needle valve	SS316L		
6.	Light glass	SS316L		
7.	Product transfer valves	SS316L		
8.	Vent and Vacuum valves	SS316L		
9.	Sight Glass	SS316L		
10.	Vent Filter	SS316L		
11.	Conical Filter	SS316L		
12.	Spray Ball	SS316L		
13.	Nozzle N3, Spray ball	SS316L		
14.	Nozzle N6, PAD	SS316L		
15.	Nozzle N8, Flange	SS316L		
Product Non-Contact Parts				
16.	Jacket shell & cone	SS 304		
17.	Insulation shell cladding	SS 304		
18.	Insulation cone bottom cladding	SS 304		



PHARMA DEVILS

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

PROTOCOL No.:

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
19.	Raw water tank shell & lid	SS 304		
20.	Screw jack	SS 304		
21.	Jacket- Hot water inlet	SS 304		
22.	Jacket safety relief valve	SS 304		
23.	Nozzle N4, Vent Filter	SS304		
24.	Nozzle N5, Pipe TC	SS304		
25.	Nozzle N9, Pipe Socket	SS304		
Water Mixer Vessel				
Product Contact Parts				
1.	Vessel Shell	SS 316L		
2.	Vessel Top Dish	SS 316L		
3.	Vessel Bottom Cone	SS 316L		
4.	Agitator Shaft	SS 316L		
5.	Propeller Impeller	SS 316L		
6.	Bottom Valve	SS 316L		
7.	Nozzle N1, Pipe TC	SS 316L		
8.	Nozzle N3 Pipe TC	SS 316L		
9.	Nozzle N6, Flange	SS 316L		
10.	Nozzle N8, Pipe Socket	SS 316L		
Product Non-Contact Parts				
11.	Vessel Jacket Shell	SS304		
12.	Vessel Jacket Cone	SS304		
13.	Insulation Shell Cladding	SS304		



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**INSTALLATION QUALIFICATION
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MULTI MIX MANUFACTURING PLANT**

PROTOCOL No.:

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
14.	Insulation Dish Cladding	SS304		
15.	Jacket Safety Needle Valve	SS 304		
16.	Jacket Safety Relief Valve	SS 304		
17.	Jacket – Hot water inlet	SS 304		
18.	Jacket – Hot water outlet	SS 304		
19.	Nozzle N4, Pipe TC	SS 304		
20.	Nozzle N5, Pipe Socket	SS 304		
21.	Nozzle N7, Flange	SS 304		
22.	Nozzle N9, Pipe Socket	SS 304		
Storage Tank				
1.	Shell	SS 316L		
2.	Top Lid & bottom dish	SS 316L		
3.	Pipe TC (N1, N2, N3, N4)	SS 316L		

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By:
Manager QA
Sign/Date:.....



PHARMA DEVILS

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

PROTOCOL No.:

8.7 Safety Verification:

CRITICAL VARIABLES	DESIGN CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Moving Parts	The Motor, Gearbox and Gear drive should be completely enclosed in a metal casing.		
Emergency Stops	Should be easily accessible location for operator		
Earthing	Proper earthing should be provided to the machine body.		
Electrical Safety	Overload Relays and Fuses should be incorporated at the necessary locations in the circuit.		
Safety Interlocks	The Safety Interlocks should be correctly incorporated as per the process flow and inter-linkages.		

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:

The Principle Reference is the following:

- 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:

- Purchase Order
- MOC & Calibration certificate
- P & ID
- GA Drawing
- 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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PHARMA DEVILS

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

PROTOCOL No.:

14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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PHARMA DEVILS

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

PROTOCOL No.:

16.0 ABBREVIATIONS:

Short Form	Expanded Form
BSP	British Standard Pipe
cGMP	Current Good Manufacturing Practices
P & ID	Piping and Instrumentation Diagram
Kg / hr	Kilogram per hour
m ³ / hr	Cubic meter per hour
°C	Degree Centigrade
ID	Inner Diameter
HT	Height
THK	Thickness
NFLP	Non-flame proof
Mt	Meter
%	Percentage
MS	Mild Steel
S. No.	Serial Number
CQA	Corporate Quality Assurance
db	Decibel
DQ	Design Qualification
GA	General Arrangement
HP	Horse Power
Hz	Hertz
Ltd	Limited
mm	Millimeter
MOC	Material of Construction
PT-100	Platinum-100
PVT.	Private
RPM	Revolution per Minute
SS	Stainless Steel
TC	Triclover
V	Volt
VFD	Variable Frequency Drive
SWG	Standard water gauge



PHARMA DEVILS

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

PROTOCOL No.:

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)			