



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

PROTOCOL No.:

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

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 prepare the Design Qualification document on basis of User Requirement Specification, Purchase Order and information provided by Supplier.
- To ensure that all critical aspects of equipment / product requirement, cGMP and safety have been considered in designing the Equipment and is properly documented.
- To specify the performance basis for acceptance of equipment.

3.0 SCOPE:

- The Scope of this qualification document is limited to the Design Qualification for MULTI MIX MANUFACTURING PLANT procured from Bectochem Consultants & Engineers Pvt. Ltd.
- The Equipment shall operate under the Controlled Environmental Conditions as per the cGMP requirements.
- The drawings and P & ID's provided by Vendor shall be verified during Design Qualification.



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4.0 RESPONSIBILITY:

The qualification 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 Authorization of Design Qualification Protocol cum Report.• Assist in the verification of Critical Process Parameter, Drawings, as per the Specification.• Co-ordination with Production and Engineering to carryout Design Qualification.• Monitoring of Design Qualification activity.• Review of Design Qualification Protocol cum Report after Execution.
Production	<ul style="list-style-type: none">• Review & Approval of Design Qualification Protocol cum Report.• Assist in the verification of Critical Process Parameter, Drawings, as per the Specification.• Review of Design Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review of Design Qualification Protocol cum Report.• Assist in the Preparation of the Protocol cum Report.• To co-ordinate and support the Activity.• To assist in Verification of Critical Process Parameter, Drawings, as per the Specification i.e.<ul style="list-style-type: none">• GA Drawing• Specification of the sub-components / bought out items, their Make, Model, Quantity and Backup Records / Brochures.• Details of Utilities• Identification of components for Calibration• Material of Construction of all components• Brief Equipment Description• Safety Features and Alarms• Review of Design Qualification Protocol cum Report after Execution.



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5.0 PROJECT REQUIREMENTS:

To confirm the safe delivery of the equipment from the supplier site. To ensure that no unauthorized and / or unrecorded design modification shall take place. If at any point in time, any change is desired in the mutually agreed design, Change Control procedure shall be followed and documented.

The Compounding Vessel, its associated components and stirrer are designed to process pharmaceutical.

Products in accordance with cGMP principles.

6.0 BRIEF EQUIPMENT DESCRIPTION:

The Multi Mix Manufacturing Plant with load cell 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



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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.

7.0 EQUIPMENT SPECIFICATION:

The specification of Multi-mix manufacturing plant is based on the user requirement specification prepared. The equipment specification shall be provided by the equipment manufacturer.



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8.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS / PRODUCT PARAMETERS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
<p>Application: The Multi-Mix mfg. Plant should be able to Manufacture cosmetic / Lotions / Creams & Gel</p>	<p>Multi-Mix mfg. Plant should meet the requirement for Manufacture Multi mix / Lotions / Creams & Gel ointment. (To be assured by Supplier).</p>	<p>Process & cGMP Requirement</p>
<p>Working: Working of Multi-Mix manufacturing Plant</p>	<p>Working is Vibration Free & free from any unwanted sound.</p>	<p>Process Requirement</p>
<p>Electrical Control Panel</p>	<p>The system should have Electrical Control Panel.</p> <ol style="list-style-type: none"> 1. Main Switch, Electrical digital temperature indicator for all vessels 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 9. Emergency Push button 	<p>Design & Process Requirement</p>

**Verified By
(Quality Assurance)**

Sign & Date:.....



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8.2 UTILITY REQUIREMENTS / LOCATION SUITABILITY:

CRITICAL VARIABLES		ACCEPTANCE CRITERIA	REFERENCE
Main Mixer	Electric Power	415 V / 3 Phase / 50 Hz	Design Requirement
	Steam	10 kg / hr	Design Requirement
	Vacuum Pump	1 m ³ / hr	Design Requirement
Wax Phase Vessel	Electric power	415V / 3PH / 50 Hz	Design Requirement
	Steam	6 kg / hr	Design Requirement
Room Condition		Temperature: NMT 25 °C RH: NMT 55%	Process Requirement

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TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

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



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Noise levels	At distance of 1 mt from noise source. Noise level Below 80 db over source operative period.	Design requirement
Dust	System is equipped with TC end connection. Operation is dust free or inlet / outlet / vent ports with quick clamp able provision to connect to dust eliminating equipment	Design requirement
Cleaning requirements	Parts easily assessable for cleaning. Vessel Body is washable.	Design requirement
Gasket	Food grade Silicon gaskets used in Sealing valves which are non-shredding, process compatible washable and easily accessed.	Design requirement
Critical Instruments	Correctly calibrated and certified for the intended use.	Design requirement
Product Temperature Sensor with Transmitter and Thermowell		
Make	Sai Tech.	Design requirement
Model	PT-100	Design requirement
MOC	SS316	Design requirement
Pressure Gauge		
Make	Baumer	Design requirement
Range	0-10 Kg/ cm ²	Design requirement
Size	4" Dial, 1/2" BSP	Design requirement
MOC	SS316 L	Design requirement
Electrical Power		
Capacity	0.5 HP	Design requirement
Connection Type / Voltage	415 Volts / 50 Hz	Design requirement
Steam		
Capacity	6 Kg/ hour	Design requirement
Connection Type	15 NB (each)	Design requirement
2. Water Phase Vessel		
Gross Capacity	40 Liters	Design requirement
Working Capacity	30 Liters	Design requirement
Maximum Operating Pressure	Vessel – Atmospheric, Jacket: 3.5 Kg / cm ²	Design requirement
Design Pressure	Vessel – Atmospheric, Jacket: 4.5 Kg / cm ²	Design requirement
Hydro-Test Pressure	Vessel – Water Fill up, Jacket: 4.0 Kg / cm ²	Design requirement



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Operating Temperature	Vessel – 100 °C, Jacket: 120 °C	Design requirement
Design Temperature	Vessel – 120 °C, Jacket: 150 °C	Design requirement
Corrosion Allowance	Nil	Design requirement
Joint Efficiency (Shell / Disc)	0.7	Design requirement
Shell	350 mm ID x 400 mm HT x 3 THK	Design requirement
Top	400 mm ID, Loose lid 16 SWG	Design requirement
Bottom	30° Cone x 3 THK	Design requirement
Jacket dish	30° Cone x 3 THK	Design requirement
Jacket Shell	425 mm ID x 300 mm HT x 3 THK	Design requirement
Insulation	50 THK, Mineral Wool	Design requirement
Cladding	16 SWG SS304	Design requirement
Surface finish of contact parts	Mirror finish, 240 grit level	Design requirement
Surface finish of non-contact parts	Matt finish, 180 grit level	Design requirement
Agitator marine propeller hollow type	RPM: Maximum 960	Design requirement
	MOC: SS316	Design requirement
	Motor: 05 HP, Non FLP, Single speed hollow shaft motor, Sweep Dia. of marine propeller 130 mm	Design requirement
	Mounting: Entire assembly mounting on G bracket to mount inclined agitator	Design requirement
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.	Design requirement
Exposed Threaded Fasteners	No threads exposed, Dome bolts are used.	Design requirement
Crevice / corners	No crevices. Rounded corners smooth surfaces.	Design requirement
Noise levels	At distance of 1 mt from noise source. Noise level Below 80 db over source operative period.	Design requirement
Dust	System is equipped with TC end connection. Operation is dust free or inlet / outlet / vent ports with quick clamp able provision to connect to dust eliminating equipment	Design requirement
Cleaning requirements	Parts easily assessable for cleaning. Vessel Body is washable.	Design requirement



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Gasket	Food grade Silicon gaskets used in Sealing valves which are non-shredding, process compatible washable and easily accessed.	Design requirement
Critical Instruments	Correctly calibrated and certified for the intended use.	Design requirement
Product Temperature Sensor with Transmitter and Thermowell		
Make	Sai Tech.	Design requirement
Model	PT-100	Design requirement
MOC	SS316	Design requirement
Pressure Gauge		
Make	Baumer	Design requirement
Range	0-10 Kg/ cm ²	Design requirement
Size	4" Dial, 1/2" BSP	Design requirement
MOC	SS316 L	Design requirement
Electrical Power		
Capacity	0.5 HP	Design requirement
Connection Type / Voltage	415 Volts / 50 Hz	Design requirement
Steam		
Capacity	6 Kg/ hour	Design requirement
Connection Type	15 NB (each)	Design requirement
3. Main Manufacturing and Vessel		
Gross Capacity	75 Liters	Design requirement
Working Capacity	60 Liters	Design requirement
Maximum Operating Pressure	Vessel – Atmospheric, Jacket: 3.5 Kg / cm ²	Design requirement
Design Pressure	Vessel – Atmospheric, Jacket: 4.5 Kg / cm ²	Design requirement
Hydro-Test Pressure	Vessel – Water Fill up, Jacket: 4.0 Kg / cm ²	Design requirement
Operating Temperature	Vessel – 100 °C, Jacket: 120 °C	Design requirement
Design Temperature	Vessel – 120 °C, Jacket: 150 °C	Design requirement
Corrosion Allowance	Nil	Design requirement
Joint Efficiency (Shell / Disc)	0.7	Design requirement
Product Contact Part	SS316	Design requirement
Electrical Rating	415 V, 50 Hz, 3 Phase	Design requirement



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Vessel shape	The vessel is vertical cylindrical jacketed and insulated. Mounted on legs	Design requirement
	Polished, Ra ≤ 0.8 (equivalent to 240 grit finish)	Design requirement
	Seal Quality: Food grade silicon	Design requirement
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.	Design requirement
	MOC: SS304	Design requirement
Insulation and Cladding	MOC: SS304, Material of insulation: Mineral wool	Design requirement
Anchor Agitator	MOC: SS 316	Design requirement
	Design: Special blade design helps in bringing the material from the sides to the center. Also continual scrapping of mass along the mass ensure better heat transfer rate. Scrapping blade covers 100 % heat transfer area.	Design requirement
	Frequency drive is provided for varying the RPM of the mixer.	Design requirement
	The shaft is supported by a bearing house with 2 taper roller bearings back to back	Design requirement
	Motor: 3 HP, 1440 RPM, Non-flame proof	Design requirement
	Single dry mechanical seal	Design requirement
	PTFE scrappers are provided on the anchor. These scrappers remain in contact with the vessel surface providing 100 % sweep.	Design requirement
Bottom Valve	65 mm nominal bore	Design requirement
	SS316	Design requirement
Finish	SS Product contact parts internally finished to 240 grit (mirror finish). SS parts externally finished to 180 grit (matt finished).	Design requirement
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.	Design requirement
Exposed Threaded Fasteners	No threads exposed, Dome bolts are used.	Design requirement
Crevices / corners	No crevices. Rounded corners smooth surfaces.	Design requirement



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Noise levels	At distance of 1 mt from noise source. Noise level Below 80 db over source operative period.	Design requirement
Dust	System is equipped with TC end connection. Operation is dust free or inlet / outlet / vent ports with quick clamp able provision to connect to dust eliminating equipment	Design requirement
Cleaning requirements	Parts easily assessable for cleaning. Vessel Body is washable.	Design requirement
Gasket	Food grade Silicon gaskets used in Sealing valves which are non-shredding, process compatible washable and easily accessed.	Design requirement
Critical Instruments	Correctly calibrated and certified for the intended use.	Design requirement
Main shell	MOC: SS316 Inner Diameter: 470 mm Thickness:4 mm Make: BCEPL	Design requirement
Top Dish	MOC: SS316 Inner Diameter: 470 mm 10 % Std. Torrispherical Dish Make: BCEPL	Design requirement
Bottom Cone	MOC: SS304 Inner Diameter: 470 mm Thickness: 4 mm Conical Shape Make: BCEPL	Design requirement
Jacket Shell	MOC: SS304 Inner Diameter: 558 mm Thickness: 3 mm Make: BCEPL	Design requirement
Jacket Cone	MOC: SS304 Inner Diameter: 558 mm Thickness: 3 mm Conical Shape Make: BCEPL	Design requirement
Insulation Shell Cladding	MOC: SS304 14" SWG Make: BCEPL	Design requirement
Insulation Cone Cladding	MOC: SS304 14" SWG Shape: Conical Bottom Make: BCEPL	Design requirement
Insulation	Thickness: 40 mm MOC: Mineral Wool Make: BCEPL	Design requirement



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Earthing Boss	MOC: SS 304 Qty. 2 Nos. Make: BCEPL	Design requirement
Agitator Shaft	MOC: SS 316 Make: BCEPL	Design requirement
Anchor Impeller	MOC: SS316 30 x 6 mm thick plate Make: BCEPL	Design requirement
Gearbox	Sr. No.: W63 Make Bonfiglioli	Design requirement
Hydraulic Column	1 HP, 60 Bore x 300 stroke Make: BCEPL	Design requirement
Jacket Needle Valve	MOC: SS 304, ½” BSP Manually Operated Needle Valve Make: BCEPL	Design requirement
Jacket Safety Relief Valve	MOC: SS 304, Safety Relief Valve, ½” BSP Make: Darshan	Design requirement
Jacket Inlet	MOC: SS 304, 15 NB, Manually Operated Ball Valve Make: Jekon	Design requirement
Jacket Outlet	MOC: SS 304, 15 NB, Pneumatically Operated Ball Valve Make: Jekon	Design requirement
Product Transfer valves	MOC: SS 316, 1”, Pneumatically Actuated Butterfly Valve Make: Jekon	Design requirement
Vent & Vacuum valves	MOC: SS 316, ½”, Manually Operated Ball Valve Make: Jekon	Design requirement
Vent Filter	MOC: SS 316, mounting stem, 5 Micron, 1” TC Make: Blinex	Design requirement
Mechanical Seal	Single Cartridge, Dry Mech. Seal Make: Hi-Fab	Design requirement
Conical Filter	MOC: SS 316 housing, 4” to 1” TC End with 100 Mesh filter Make: BCEPL	Design requirement
Lobe Pump	MOC: SS 316, 1.0 HP, 1440 RPM, NFLP, 3 Meter Head, SS 304 Trolley Mounted Make: Jakim	Design requirement
BOTTOM ENTRY HOMOGENIZER	2 HP, 2880 RPM, NFLP, 3 Phase, 415V, 2” TC (both ports) Make: BCEPL	Design requirement
Metering Pump	MOC: SS 316, 200 Litres per Hour, 1 HP, 1440 RPM, NFLP, Make: Jakim	Design requirement



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Vacuum Pump	1 HP, 3 Phase, 1440 RPM, Non FLP, Water Ring Type Make: Jakim	Design requirement
4. Storage Vessel		
Gross Capacity	75 Liters	Design requirement
Working Capacity	60 Liters	Design requirement
Type	Cylindrical, Vertical & Non-jacketed top loose lid, conical bottom. Vessel is supported with SS304 legs	Design requirement
Shell	450 mm ID x 350 mm HT	Design requirement
Top	450 mm ID, Loose lid 16 sw	Design requirement
Bottom	30° Cone	Design requirement
Steam Control Valves	Solenoid valve ON / OFF type (Pneumatically actuated) Qty. 01 No. Make: AVCON	Design requirement
Control panel	Push button type, Carbon steel painted, Floor resting, MS powder coated, Non-flame proof	Design requirement
Display and Control	RPM indicator, Cowl disperser, Temperature indicator cum controller	Design requirement
RPM	Variable Frequency Drive Make: Mitsubishi for anchor	Design requirement
Temperature sensor	Product and Jacket PT 100 sensor	Design requirement
5. Transfer Pump – Twin lobe type		
Type	Mounted on trolley with castor wheels, Nylon PU coated	Design requirement
Capacity (Flow rate)	3000 Liters / hr, Basis: Water	Design requirement
Head	2.0 Meter	Design requirement
Pressure	3 Kg / Cm ²	Design requirement
Suction connection	1 ^{1/2} "	Design requirement
Discharge connection	1 ^{1/2} "	Design requirement
MOC, Contact parts	SS316	Design requirement
Motor	1 HP, 720 RPM	Design requirement
Mounting	Skid mounted on common SS frame.	Design requirement
6. Storage Tank		
Gross Capacity	75 Liters	Design requirement



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Working Capacity	50 Liters	Design requirement
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.	Design requirement
Exposed Threaded Fasteners	No threads exposed, Dome bolts are used.	Design requirement
Crevice / corners	No crevices. Rounded corners smooth surfaces.	Design requirement
Noise levels	At distance of 1 mt from noise source. Noise level Below 80 db over source operative period.	Design requirement
Dust	System is equipped with TC end connection. Operation is dust free or inlet / outlet / vent ports with quick clamp able provision to connect to dust eliminating equipment	Design requirement
Cleaning requirements	Parts easily assessable for cleaning. Vessel Body is washable.	Design requirement
Gasket	Food grade Silicon gaskets used in Sealing valves which are non-shredding, process compatible washable and easily accessed.	Design requirement
Critical Instruments	Correctly calibrated and certified for the intended use.	Design requirement
Shell	ID - 470 mm, Thickness - 4 mm MOC – SS316 Make – BCEPL	Design requirement
Top Lid	Flat loose lid with locking arrangement, MOC – SS316 Make – BCEPL	Design requirement
Bottom Cone	ID - 470 mm, Thickness - 4 mm, Conical bottom, MOC – SS316 Make – BCEPL	Design requirement
Leg Support	MOC - SS 304 Make – BCEPL	Design requirement
Product Transfer valves	SS 316L, 1", Manually Operated Butterfly Valve Make –Jekon	Design requirement
Nozzle N1	Product Inlet	Design requirement
Nozzle N3	Tank Outlet	Design requirement



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Product Pipe Line	<ol style="list-style-type: none"> 1. Transfer of product from water phase vessel to multipurpose mixer bowl under vacuum. 2. Transfer of product from Wax phase vessel to multipurpose mixer bowl under vacuum. 3. Mixer to storage vessel through lobe pump 4. Storage vessel to hopper of filling machine through transfer pump 	Design requirement
Electrical Control Panel	<ol style="list-style-type: none"> 10. Main Switch, Electrical digital temperature indicator for all vessel 11. DOL Starter for metering pump 12. Fuses for all motors 13. Indicator lamps for main ON/OFF with selector switch 14. DOL Starter for lobe pump 15. DOL starter for propeller agitators 16. Starter with overload relay for cowl disperser, Homogenizer and Anchor type agitator 17. Potentiometer for speed control of main anchor stirrer, cowl disperser 	Design requirement

7. High Shear Mixer Emulsifier (Homogenizer)

Model	OL 02	Design requirement
Type	Skid mounted with T.C clamp	Design requirement
Motor Type	2 HP, 2880 RPM, Non-FLP	Design requirement
Supply Voltage	415 V, 3 Phase, 50 Hz	Design requirement
Control	ON/OFF	Design requirement
Suction connection	1.5"	Design requirement
Discharge connection	1"	Design requirement

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8.3 MATERIAL OF CONSTRUCTION

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION
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
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

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

PROTOCOL No.:

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION
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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PROTOCOL No.:

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION
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

Verified By

(Quality Assurance)

Sign & Date:.....



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

PROTOCOL No.:

8.4 SAFETY:

CRITICAL VARIABLES	DESIGN CRITERIA	REFERENCE
Moving Parts	The Motor, Gearbox and Gear drive are completely enclosed in a metal casing.	Safety Requirement
Emergency Stops	Easily accessible location for operator	Safety Requirement
Earthing	Proper earthing is provided to the machine body.	Safety Requirement
Noise Levels	Equipment designed so as not to exceed 80 decibels averaged over source operative period. At distance of 1 mtr from the noise source at a height of 1.5 mtr.	Safety Requirement
Electrical Safety	Overload Relays and Fuses incorporated at the necessary locations in the circuit.	Safety Requirement
Safety Interlocks	The Safety Interlocks correctly incorporated as per the process flow and inter-linkages.	Safety Requirement
Alarms		
Anchor motor fault	Occurs if anchor motor is ON and feedback is not received within 3 sec.	Safety Requirement
Power pack motor fault	Occurs if power pack motor is ON and feedback is not received within 3 sec.	Safety Requirement
Homogenizer motor fault	Occurs if homogenizer motor is ON and feedback is not received within 3 sec.	Safety Requirement
Lobe pump fault	Occurs if lobe pump motor is ON and feedback is not received within 3 sec.	Safety Requirement
Metering motor fault	Occurs if metering motor is ON and feedback is not received within 3 sec.	Safety Requirement
Vacuum pump fault	Occurs if Vacuum pump motor is ON and feedback is not received within 3 sec.	Safety Requirement
Propeller wax motor fault (wax entry)	Occurs if Propeller motor is ON and feedback is not received within 3 sec.	Safety Requirement
Propeller water motor fault (water entry)	Occurs if Propeller motor is ON and feedback is not received within 3 sec.	Safety Requirement
Mechanical seal flow switch fault	Occurs if flow switch is ON and feedback is not received.	Safety Requirement
Main mixer top dish lower proxy fault	Occurs if lid is not in down position	Safety Requirement
Emergency stop fault	Occurs if emergency stop push button is pressed	Safety Requirement



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PROTOCOL No.:

CRITICAL VARIABLES	DESIGN CRITERIA	REFERENCE
Product Temperature high; 1. Main mixer 2. Wax phase vessel 3. Water phase vessel	Occurs if product temperature crosses high set value	Safety Requirement
Main mixer top dish open	Occurs if lid is open and motor ON command is given	Safety Requirement

User Level Accessibility

Mode	Level 1 (Operator)	Level 2 (Supervisor)	Level 3 (Manager)
Auto	√	√	√
Maintenance	X	X	√
Manual	X	√	√
Data Entry	Edit	X	√
	Load	X	√
	Change Password	√	√
Date & Time entry	X	X	√

√ – Accessible

X – Not Accessible

**Verified By
(Quality Assurance)**

Sign & Date:.....



PHARMA DEVILS

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

PROTOCOL No.:

8.5 VENDOR SELECTION:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Selection of Vendor for Multi-mix manufacturing plant	Selection of Vendor is done on the basis of review of vendor. Criteria for review includes Vendor Background (General / Financial), Technical know -how, Quality Standards, Inspection of Site, Costing, feedback from Market.	cGMP Requirement

- Reference:** (1) User Requirement Specifications (URS).
(2) Design & Functional Specifications provided by Vendor.

**Verified By
(Quality Assurance)**

Sign & Date:.....



PHARMA DEVILS

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

PROTOCOL No.:

9.0 DOCUMENTS TO BE ATTACHED:

- Purchase Order Copy.
- P & ID – Ointment Plant
- GA Drawing
- Component list
- Instrument list
- Utility list
- MOC certificates
- Vendor documents

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10.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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11.0 ANY CHANGES MADE AGAINST THE FORMALLY AGREED PARAMETERS:

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12.0 RECOMMENDATION:

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PHARMA DEVILS

**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
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PROTOCOL No.:

13.0 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
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



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**DESIGN QUALIFICATION
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FOR
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PROTOCOL No.:

14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			