



PHARMA DEVILS

**INSTALLATION QUALIFICATION PROTOCOL
FOR
MAIN MANUFACTURING MIXING VESSEL**

PROTOCOL No.:

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1.0 PROTOCOL APPROVAL:

Signing of this approval page of Protocol indicates agreement with the qualification approach described in this document. If modification to the qualification approach becomes necessary, an addendum shall be prepared and approved. The protocol cannot be used for execution unless approved by the following authorities.

This Installation Qualification protocol of Main Manufacturing Mixing Vessel has been reviewed and approved by the following persons:

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
PREPARED BY			QUALITY ASSURANCE		
			QUALITY ASSURANCE		
REVIEWED BY			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		

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2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of developing and executing this protocol is to collect sufficient data pertaining to the Main Manufacturing Mixing Vessel and define the installation qualification requirements and acceptance criteria for the Main Manufacturing Mixing Vessel. Successful completion of these installation qualification requirements will provide assurance that the Main Manufacturing Mixing Vessel was installed as required in the manufacturing area.

The Qualification of Main Manufacturing Mixing Vessel performed in view of ointment area of manufacturing facility of

2.2 PURPOSE:

The purpose of this protocol is to establish documentary evidence to ensure that the Main Manufacturing Mixing Vessel received matches the Design specification and also to ensure that it is properly and safely installed.

2.3 SCOPE:

This Protocol is applicable to installation of Main Manufacturing Mixing Vessel in Ointment area of the manufacturing facility at

2.4 RESPONSIBILITY:

In accordance with protocol, following functions shall be responsible for the qualification of system.

Execution Team (Comprising members from Production, Engineering and Quality Assurance) and their responsibilities are following:

- Prepares the qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures on system Qualification.
- Distributes the finalized protocol for review and approval signatures.
- Execution of Qualification protocol.
- Review of protocol, the completed qualification data package, and the final report.



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- The installation checks, operational checks, calibration, SOP identification, identification features, identification of utility supply shall be carried out by engineering persons
- The production operator/supervisor shall carry out the cleaning and operation of machine.

Head – Production/Engineering:

- Review of protocol, the completed qualification data package, and the final report.
- Assist in the resolution of validation deficiencies.

Head – Operation and Quality Assurance:

- Review and approval of protocol, the completed qualification data package, and the final report.



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3.0 ACCEPTANCE CRITERIA:

- 3.1 The Main Manufacturing Mixing Vessel shall meet the system description given in design qualification.
- 3.2 The Main Manufacturing Mixing Vessel shall meet with the acceptance criteria mentioned under the topic “Identification of major components”
- 3.3 All material of constructions of the contact parts to be checked as per the specifications.

4.0 REQUALIFICATION CRITERIA:

The machine shall be requalified if

- There are any major changes in system components which affect the performance of the system
- After major breakdown maintenance is carried out.
- As per revalidation date and schedule



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5.0 INSTALLATION QUALIFICATION PROCEDURE:

5.1	SYSTEM DESCRIPTION:
1	Equipment Name : Main Manufacturing Mixing Vessel
2	Supplier/Manufacturer : Bectochem Consultants & Engineers Pvt. Ltd.
3	Model : GMP Compliant
4	Serial no. : NA
5	Location : Manufacturing

The Main Manufacturing Mixing Vessel consists of Following Components:

1. Ointment Main Manufacturing Mixing Vessel 1765 ltrs comprises of top dish end and bottom dish end welded with central cylindrical shell.
2. Ointment Main Manufacturing Mixing Vessel 1765 ltrs is provided with jacket (designed for steam and cold water circulation) and glass wool insulation at shell and bottom dish end for heating of vessel. This Main Manufacturing Mixing Vessel is practically designed for the manufacturing and holding of final product.
3. Top entry agitator of anchor type with scrapper is provided inside the vessel for mixing. It is provided with a VFD for speed variation.
4. The top dish end is provided with nozzles as per the service requirement and this top dish end is lifted with the help of hydraulic cylinder lifting arrangement for ease in cleaning the tank.
5. An in line homogenizer is provided at the outline of the Manufacturing Mixing Vessel. The pipeline and valves required for the recirculation are provided. The function of in line homogenizer is to reduce the particle size, solubilize the solution and provided vigorous mixing.
6. Ointment Main Manufacturing Mixing Vessel 1765 ltrs is mounted on load cells that are used to measure the load on vessel.
7. The ointment Main Manufacturing Mixing Vessel 1765 ltrs is provided with all pipes, pipe fittings and valves with TC fittings and silicon gaskets.
8. The vessel is designed for steam circulation.



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5.2 INSTRUCTION FOR FILLING THE CHECKLIST

- 5.2.1 In case of identification of major component actual observation should be written in specified location.
- 5.2.2 In case of the compliance of the test actual observation should be written in specified location.
- 5.2.3 For identification of utilities actual observation should be written in specified location.
- 5.2.4 Give the detailed information in the summary and conclusion part of the installation Qualification report.
- 5.2.5 Actual observation of the component should be written in specified location.
- 5.2.6 Whichever column is blank or not used 'NA' shall be used.



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5.3 INSTALLATION CHECKLIST:

Installation checklist is as follows:

S.No.	Statement	Method Of Verification	Actual Observation	Checked By Sign/Date
1	Verify purchase order copy and write down P.O. number	Visually/ Documental		
2	Verify that the "As Built" drawing is complete and represents the design concept.	Visually/ Physically		
3	Verify that there is no observable physical damage	Physically		
4	Examine All access ports are cleared of any debris.	Physically		
5	Verify that all components are properly assembled, securely anchored and shock proof.	Physically		
6	Verify that all electrical connections are properly done and safe	Physically		
7	Verify that the equipment is properly earthed	Physically		
8	Verify that utility line is properly connected	Physically		
9	Verify the proper leveling of equipment	Physically		
10	Verify that there is sufficient space provided for operation, cleaning, preventive maintenance	Physically		
11	Equipment/system identification no. Is visible	Physically		

Remark: -----

Reviewed by (Sign/Date)



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5.4 IDENTIFICATION OF MAJOR COMPONENTS:

Describe each critical component and check them and fill the inspection checklist.

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Tank Design	Make	Bectochem Consultants & Engineers Pvt. Ltd.	Visually/ Technical Specification		
	Gross Capacity	2150 Liters	Visually/ Technical Specification		
	Working Capacity	1765 Liters	Visually/ Technical Specification		
Motor	Make	Bharat Bijlee	Visually / Physically		
	Sr. No.	To be recorded	Visually / Physically		
	Spec.	10 HP, 1450 RPM, NON-FLP, Frame 132 M	Visually / Physically		
Main Shell	Make	BCEPL	Physically/ Technical Specification		
	Size	8 Thk	Physically/ Technical Specification		
Top Dish End	Make	BCEPL	Physically/ Technical Specification		
	Size	8 Thk	Physically/ Technical Specification		



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System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Bottom Cone	Make	BCEPL	Physically/ Technical Specification		
	Size	8 Thk	Physically/ Technical Specification		
Gear Box	Make	NORD	Visually / Physically		
	Spec.	SK 9042.1 AXF IEC 132	Visually / Physically		
	Ratio	40.54:1	Visually / Physically		
Jacket Shell	Make	BCEPL	Physically/ Technical Specification		
	Size	6 Thk	Physically/ Technical Specification		
Jacket Cone	Make	BCEPL	Physically/ Technical Specification		
	Size	6 Thk	Physically/ Technical Specification		
Insulation Shell/Cone	Make	BCEPL	Physically/ Technical Specification		
	Size	5 Thk	Physically/ Technical Specification		
Leg Pipe	Make	BCEPL	Physically/ Technical Specification		
	Size	100 NB X SCH. 40	Physically/ Technical Specification		



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System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Make				
Anchor Shaft	Make	BCEPL	Physically/ Technical Specification		
	Size	Ø 80	Physically/ Technical Specification		
Paddle Sweep	Make	BCEPL	Physically/ Technical Specification		
	Size	Ø 520 X 12 Thk	Physically/ Technical Specification		
Static Baffle Pipe	Make	BCEPL	Physically/ Technical Specification		
	Size	80 NB X SCH. 40	Physically/ Technical Specification		
Baffle Plate	Make	BCEPL	Physically/ Technical Specification		
	Size	10 mm	Physically/ Technical Specification		
Base Plate	Make	BCEPL	Physically/ Technical Specification		
	Size	12 mm	Physically/ Technical Specification		
Sensor PT 100	Make	Eureka	Visually / Physically		
	Size	½" BSP	Visually / Physically		
	Qty.	01 No.	Visually / Physically		



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System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Compound Gauge	Make	Waaree	Visually / Physically		
	Spec.	4" Dial, -1 to 5 kg/cm ²	Visually / Physically		
	Qty.	01 No.	Visually / Physically		
Pressure Gauge with Safety Valve & Needle Valve	Make	Baumer	Visually / Physically		
	Spec.	½" Pressure Gauge, Safety Valve & Needle Valve	Visually / Physically		
	Range	0-7 Kg/cm ²	Visually / Physically		
	Qty.	01 Set	Visually / Physically		
Lobe Pump Motor	Make	Belko	Visually / Physically		
	Spec.	2 HP	Visually / Physically		
	Sr. No.	To be recorded	Visually / Physically		
Vacuum Pump with Motor	Make	Newgenre	Visually / Physically		
	Spec.	7.5 HP, 1450 RPM	Visually / Physically		
	Sr. No.	To be recorded	Physically		
Mechanical Seal	Make	Hi-Fab	Physically/ Technical Specification		
	Spec.	Ø 70, SSDB E2	Physically/ Technical Specification		



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System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Inline Homogenizer Motor	Make	Bharat Bijlee	Visually / Physically		
	Spec.	15 HP, 2920 RPM, 337-450 V	Visually / Physically		
	Sr. No.	To be recorded	Visually / Physically		
Proximity Sensor	Make	Katlax	Visually / Physically		
	Model	M18, PNP NO	Visually / Physically		
	Spec.	10-30 VDC, Qty.- 02 Nos.	Visually / Physically		
Hydraulic Power Pack Motor	Make	HMM	Visually / Physically		
	Spec.	3 Ph, 415 V, 50 Hz, 1.5 HP, 1410 RPM	Visually / Physically		
Hydraulic Pressure Gauge	Make	Dynamic	Visually / Physically		
	Range	0-140 Kg/Cm ²	Visually / Physically		
Directional Solenoid Valve	Make	Yuken	Visually / Physically		
	Model	DSG-01-3C60-A240-N-50	Visually / Physically		
VFD	Make	ABB	Visually / Physically		
	Type	ACS550-01-95A-4	Visually / Physically		
	Sr. No.	To be recorded	Physically		



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System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
PLC	Make	Mitsubishi	Visually / Physically		
	Model	FX3U-48M	Visually / Physically		
Input Module	Make	Mitsubishi	Visually / Physically		
	Model	FX2N-8EX- ES	Visually / Physically		
Output Module	Make	Mitsubishi	Visually / Physically		
	Model	FX2N- 16EYR	Visually / Physically		
Nozzle Schedule					
N1	Location	Handhole	Visually / Physically		
	Size	Ø 250 X 5 Thk	Physically/ Technical Specification		
N2	Location	Inlet Hopper	Visually / Physically		
	Size	2" OD X 14 SWG	Physically/ Technical Specification		
N3	Location	Wax Inlet	Visually / Physically		
	Size	1 1/2" OD X 14 SWG	Physically/ Technical Specification		
N4	Location	Water Inlet	Visually / Physically		
	Size	1 1/2" OD X 14 SWG	Physically/ Technical Specification		



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System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
N5	Location	Bottom Outlet	Visually / Physically		
	Size	3"	Physically/ Technical Specification		
N6	Location	Vacuum Manifold	Visually / Physically		
	Size	2" OD X 14 SWG	Physically/ Technical Specification		
N7	Location	CIP Spray Nozzle	Visually / Physically		
	Size	75/38 OD X 14 SWG	Physically/ Technical Specification		
N8	Location	Steam Inlet/ Cold water outlet	Visually / Physically		
	Size	40 NB X SCH 40	Physically/ Technical Specification		
N9	Location	Steam Outlet/ Cold water Inlet	Visually / Physically		
	Size	40 NB X SCH 40	Physically/ Technical Specification		
N10	Location	Jacket Vent	Visually / Physically		
	Size	½" X SCH 40	Physically/ Technical Specification		
N11	Location	Jacket Drain	Visually / Physically		
	Size	½" X SCH 40	Physically/ Technical Specification		



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System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
N12	Location	Thermowell	Visually / Physically		
	Size	15 NB X SCH 40	Physically/ Technical Specification		
N13	Location	Spray Nozzle	Visually / Physically		
	Size	1 1/2" OD X 14 SWG	Physically/ Technical Specification		
N14	Location	Light Glass	Visually / Physically		
	Size	Ø 100	Physically/ Technical Specification		
N15	Location	Re-circulation	Visually / Physically		
	Size	2 1/2" OD X 14 SWG	Physically/ Technical Specification		
Load Cell system					
Load Cell	Make	Mettle Toledo	Physically		
	Model	SBH-1 P/N71204083	Physically		
	Sr. No.	To Be recorded	Physically		
Load cell Display	Make	Mettle Toledo	Physically		
	Model	TWS 300 Series	Physically		
HMI					
Make		Mitsubishi	Physically		
Model		E1061	Physically		

Remark: -----

Reviewed by (Sign/Date)



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5.5 VERIFICATION OF MATERIAL OF CONSTRUCTION:

Name of Components	Material of Construction	Method of Verification	Observation	Verified By Sign/Date
Main Shell	SS 316 L	By Molybdenum Kit/ Test Certificate		
Top Dish End	SS 316 L	By Molybdenum Kit/ Test Certificate		
Bottom Cone	SS 316 L	By Molybdenum Kit/ Test Certificate		
Mechanical Seal	SS 316 L	By Molybdenum Kit/ Test Certificate		
Anchor Shaft	SS 316 L	By Molybdenum Kit/ Test Certificate		
Paddle Sweep	SS 316 L	By Molybdenum Kit/ Test Certificate		
Static Baffle pipe	SS 316 L	By Molybdenum Kit/ Test Certificate		
Baffle Plate	SS 316 L	By Molybdenum Kit/ Test Certificate		
Jacket Shell	SS 304	By Molybdenum Kit/ Test Certificate		
Jacket Cone	SS 304	By Molybdenum Kit/ Test Certificate		
Insulation Shell/ Cone	SS 304	By Molybdenum Kit/ Test Certificate		
Leg Pipe	SS 304	By Molybdenum Kit/ Test Certificate		
Base Plate	SS 304	By Molybdenum Kit/ Test Certificate		

Remark: -----

Reviewed by (Sign/Date)



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5.6 IDENTIFICATION OF SUPPORTING UTILITIES:

S.No.	Utility	Method Of Verification	Observation	Checked By Sign/Date
1.	Electricity: 3 Phase, 415V & 50 Hz with neutral and proper earthing	By using clamp meter		
2.	Compressed Air	On Pressure Gauge		

Remark: -----

Reviewed by (Sign/Date)



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5.7 IDENTIFICATION OF SAFETY FEATURES:

Identify and record the safety/interlocking features (if any) and their function in following tables:

Safety Features Description	Location/Identification	Method Of Verification	Observation	Identified By Sign/Date
Earthing of motor	To avoid the accident due to the leakage current.	Visually		
Safety valve	To avoid the accident due to high pressure in the jacket.	Visually		

Remark: -----

Reviewed by (Sign/Date)



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5.8 IDENTIFICATION OF COMPONENT TO BE CALIBRATED:

Name of Components	Range	Make	ID	Location	Identified By Sign/Date

Remark: -----

Reviewed by (Sign/Date)



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5.9 IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP)

The following Standard Operating Procedures were identified as important for effective performance of Main Manufacturing Mixing Vessel operation.

S.No.	SOP Title	Verified By Sign/ Date

Remark: -----

Reviewed by (Sign/Date)



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5.10 VERIFICATION OF DRAWING AND DOCUMENTS:

Following documents are reviewed and attached as listed below:

S.No.	Drawing And Document Detail	Verified By Sign/Date

Remark: -----

Reviewed by (Sign/Date)



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5.11 ABBREVIATIONS

Following Abbreviations are used in the installation qualification protocol of Double Head Tube Filling Machine.

MOC : Material of construction

RPM : Rotation per minute

/ : Per

V : Volts

HZ : Hertz

HP : Horse Power

Amp. : Ampere

kw : Kilo watt

mm : Millimeter

°C : Degree Centigrade

FLP : Flame Proof

Spec. : Specification

Qty. : Quantity

ltrs. : Liters

BCEPL: Bectochem Consultants & Engineers Pvt. Ltd.



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5.12 DEFICIENCY AND CORRECTIVE ACTION (S) REPORT (S)

Following deficiency was verified and corrective actions taken in consultation with the Engineering Department.

Description of deficiency:

Corrective action(s) taken:

**Deviation accepted by
(Sign/Date)**

**Deviation Approved by
(Sign/Date)**



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5.13 Annexure (S)

Annexure No.

Details Of Annexure

Remarks (if any):

Done By & Date:

Verified By & Date:



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6.0 INSTALLATION QUALIFICATION FINAL REPORT:

6.1 SUMMARY:

6.2 CONCLUSION:

**Prepared By
Sign/ Date**

**Checked By
Sign/ Date**



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6.3 FINAL REPORT APPROVAL

It has been verified that all tests required by this protocol are completed, reconciled and attached to this protocol or included in the qualification summary report. All amendments and discrepancies are documented, approved and attached to this protocol. If applicable, Signature in the block below indicates that all items in this qualification report of Main Manufacturing Mixing Vessel have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved. After the successful installation qualification of the Main Manufacturing Mixing Vessel the equipment can be taken for operational qualification.

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		