



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

**PROTOCOL No.:**

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**1.0 PROTOCOL APPROVAL:**



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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 Operation Qualification protocol of Main Manufacturing Vessel has been reviewed and approved by the following persons

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

**2.0 OVERVIEW:**



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**2.1 OBJECTIVE:**

The objective of developing and executing this protocol is to collect sufficient data pertaining to the Main Manufacturing Vessel and define the qualification requirements and acceptance criteria for the machine and to prove that each operation proceeds as per design specification and the tolerances prescribed there in the document.

**2.2 PURPOSE:**

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

**2.3 SCOPE:**

The Scope of this protocol is limited to the operational Qualification of Main Manufacturing Vessel in ointment area of manufacturing facility at .....

Once the operational qualification of Main Manufacturing Vessel has been completed successfully, the equipment shall be preceded for the performance qualification procedure. Main Manufacturing Vessel consists of the following equipments.

<b>Equipment Name</b>	<b>Equipment ID</b>	<b>Specified Function</b>
Manufacturing Vessel	.....	Manufacturing and Holding of l product
Inline homogenizer	.....	To form homogeneous dispersion of two different or similar phase
Lobe Pump	.....	Transfer of final product from manufacturing to storage vessel
Vacuum pumps	NA	product transfer to manufacturing vessel

**2.4 RESPONSIBILITY:**

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



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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.
- The operational checks, calibration, SOP verification, verification of safety features, verification of utility supply shall be carried out by engineering persons and production person.
- 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.

**2.5 EXECUTION TEAM:**



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The satisfactory operation of the Main Manufacturing Vessel shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the Main Manufacturing Vessel is operational and is satisfactorily working.

Execution team is responsible for the execution of Operational of Main Manufacturing Vessel.  
Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

**3.0 ACCEPTANCE CRITERIA**



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- 3.1 The equipment shall be operational as per its specified operating instructions.
- 3.2 All SOPs for the equipment to be verified and checked.
- 3.3 Training is important to all the concerned personnel.
- 3.4 All the functionality of equipment components to be checked.
- 3.5 The RPM of motor/stirrer should be in the range of  $\pm 5\%$  deviation.

**4.0 REVALIDATION CRITERIA**

The machine shall be revalidated if

- There are any major changes, which affect the performance of equipment.
- During preventive maintenance or break down maintenance if any major components is replaced which affects the performance of equipment.
- As per revalidation date and schedule.

**5.0 OPERATIONAL QUALIFICATION PROCEDURE**



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**5.1 SYSTEM DESCRIPTION:**

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

The Manufacturing Vessel consists of Following Components:

1. Manufacturing Vessel is designed for manufacturing and holding of final product.
2. Manufacturing Vessel comprises of top dish end and bottom dish end welded with central cylindrical shell.
3. Manufacturing Vessel is provided with jacket and glass wool insulation at shell and bottom dish end for heating of vessel.
4. Top entry agitator of anchor type with scrapper is provided inside the vessel for mixing. It is provided with a VFD for speed variation.
5. The top dish end is provided with nozzles as per the service requirement and this top end is lifted with the help of hydraulic cylinder lifting.
6. Manufacturing vessel is mounted on load cells that are used to measure the load on vessel.



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- **INLINE HOMOGENISER**

Homogenizers are devices to form homogeneous solution or dispersion of two different phase or even similar phase. Three stages involves in its working principles:

**Stage-01:**

The high speed rotor opening at close tolerance to the stator draws material from conical bottom of container and subjects it to intense mixing and shearing action.

**Stage-02:**

The rotor accelerates the product towards blade periphery. There it is expelled out into body of mixer while undergoing intensive mechanical and shearing action. Simultaneously new materials are drawn into the centre of door.

**Stage-03:**

The mixture is expelled through the outlet of machine and is re-circulated through primary agitator again.

In this way homogenizer works by conversion the kinetic energy into pressure energy between stator and rotor as there is close tolerance within them so as to complete homogenize the product.

- **LOBE PUMP (Transfer Pump):**

The lobe pump is used to transfer the final product from manufacturing to storage vessel. The operation of lobe pump depend upon vacuum which is created inside two lobes as the two lobes rotate with the help of motor coupled to it, the liquid/slurry product will suck inside the rotor (lobe) and it is further transfer to outlet by means of kinetic energy.

- **VACUUM PUMP**

Vacuum pumps are used to transfer the product from Wax phase vessel and water phase vessel to manufacturing vessels.





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**5.2 INSTRUCTION FOR FILLING THE CHECKLIST**

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

**5.3 TEST INSTRUMENT DETAILS**



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This test is intended to describe the equipments/instruments and its complete details to have a traceability to the national standard which is to be used for the verification of the operation.

S.No.	Name Of Instrument	Inst. ID. Number	Calibration done on	Calibration Due date	Certificate Number

**Checked by Date:**

**Remark:** -----  
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**Reviewed by (Sign/Date)**

**5.4 Verification of Calibrated Component :**





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**5.5.1 Verification of functionality major component:**

Name of System Component	Specified Function	Method Of Verification	Observation	Verified By Sign /Date
Vessel Jacket with inlet and outlet arrangement	For circulation of steam/cool water in jacket	Visually/ Challenging		
Top Entry Agitator	For proper mixing	Visually/ Challenging		
Anchor Motor	Minimum and maximum RPM	Visually/ Challenging		
Vacuum pump	To facilitate the transfer of materials of Wax phase, Water Phase and API Vessel into manufacturing vessel	By Challenging		
Spray Ball	For cleaning the vessel.	Visually/ Challenging		
Hydraulic Cylinder	To lift the top lid of manufacturing vessel	Visually/ Challenging		
In-line homogenizer with recirculation facility	For proper mixing of final product into manufacturing vessel before being transferred to storage vessel	Visually/ Challenging		



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Name of System Component	Specified Function	Method Of Verification	Observation	Verified By Sign /Date
Lobe pump with inlet/outlet	For material to transfer to the Storage tank.	Visually/ Challenging		
Load Cell	For weight verification.	Visually/ Challenging		
Safety Valve Jacket	For safety of the vessel from over pressure	Visually/ Challenging		
UPS Supply	For continuation of operation with same set after power cut.	Visually/ Challenging		
Pneumatic valves	Smooth & proper actuation of Pneumatically operated valves	Visually/ Challenging		
Measuring/controlling Instruments	Smooth & proper functioning of Measuring Instruments	Visually/ Challenging		
Load Cell	Shall be verify by loading measured Quantity of water in vessel as _____kg _____kg _____kg _____kg _____kg	By Challenging	_____kg _____kg _____kg _____kg _____kg	

**Remark:** .....



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**5.5.2 Verification of operation key functionality**

<b>Name of System Component</b>	<b>Specified Function</b>	<b>Method Of Verification</b>	<b>Observation</b>	<b>Verified By Sign /Date</b>
Switch 'ON' the main power panel supply	Power flow shall come to the main panel	By rotating the main power switch to 'ON' position		



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Name of System Component	Specified Function	Method Of Verification	Observation	Verified By Sign /Date
Control ON/OFF turn toggle key from OFF mode to ON mode	Power comes into operating Panel (Screen touch HMI) and HMI shows the login option on screen (Single level Password Protected Touch screen HMI)	By rotating the Control ON/OFF turn toggle key		
Check the working Vessel lamp	Lamp in vessel shall glow	“ON” the lamp on touch screen HMI panel.		
Check the working Vessel lamp	Lamp in vessel shall get “OFF”	“OFF” the lamp on touch screen HMI panel.		
To lift the top lid of manufacturing vessel	Gauge of Power pack shall show the increase in pressure and Hydraulic cylinder shall start lifting the lid.	By continue pressing “Lift Up” button of touch screen HMI panel, there shall be lifting up of lid till touch of button		



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<b>Name of System Component</b>	<b>Specified Function</b>	<b>Method Of Verification</b>	<b>Observation</b>	<b>Verified By Sign /Date</b>
To lower the top lids of manufacturing vessel	Hydraulic cylinder shall start lowering.	By continue pressing “Lid Down” button of touch screen HMI panel, there shall be down ward movement of lid till touch of button		
Challenge the Minimum and Maximum working and gross capacity of vessel and verify the load cell with respect to HMI with Purified Water at ambient temperature.	<ul style="list-style-type: none"><li>• <b>Minimum Working capacity:</b> 645 Kg</li><li>• <b>Maximum Working capacity:</b> 1765 kg</li><li>• <b>Gross Capacity:</b> 2150 Kg</li></ul>	<p><b>Pre-requisite:</b> [Electronic Weighing Balance, Weight the purified water and Verify the <b>Minimum and Maximum working and gross capacity.</b> Verify the Weight Shown in HMI shall be according to cumulative weight of purified water.</p>		





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<b>Name of System Component</b>	<b>Specified Function</b>	<b>Method Of Verification</b>	<b>Observation</b>	<b>Verified By Sign /Date</b>
Start the Vacuum pump of manufacturing vessel to check the smooth and complete transfer of material from wax Phase vessel into manufacturing vessel.	Vacuum pumps shall get start and there shall be smooth and complete transfer of material from wax into manufacturing vessel.	“ON” the vacuum of manufacturing vessel, wax phase vessel outlet and manufacturing vessel wax inlet.		
Start the Vacuum pump of manufacturing vessel to check the smooth and complete transfer of material from water phase vessel into manufacturing vessel.	Vacuum pumps shall get start and there shall be smooth and complete transfer of material from water phase vessel into manufacturing vessel.	“ON” the vacuum of manufacturing vessel, water phase vessel outlet and manufacturing vessel water inlet.		
To Stop the Vacuum pump of manufacturing vessel	Vacuum pump shall stop.	“OFF” the Vacuum of manufacturing vessel.		
To Start top agitator of manufacturing vessel.	Motor shall start and agitator shall start rotating	“ON” the stirrer form Touch screen HMI and set the RPM and time		



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Name of System Component	Specified Function	Method Of Verification	Observation	Verified By Sign /Date
Verify the speed of Stirrer (0-35 RPM)	Speed of the Stirrer shall change	Verify the speed at minimum to maximum (i.e. 5, 10, 15, 20, 25, 30 & 35 RPM) by putting the value as on touch screen HMI panel. Verify with Tachometer.		
To stop top anchor of manufacturing vessel.	Motor shall stop and anchor shall stop rotating	"OFF" the stirrer from Touch screen HMI.		
Verify the Speed of In-line homogenizer	The impeller speed of In-line homogenizer shall show the 2920 RPM	Start the homogenizer and verify the homogenizer RPM.		
Check & Set the time (1-100 minutes) from the recirculation specified operating parameters of In line homogenizer	In line homogenizer Recirculation shall be operated for set time & stop after set time completion	"ON" the Recirculation from Touch screen HMI and set the time.		



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<b>Name of System Component</b>	<b>Specified Function</b>	<b>Method Of Verification</b>	<b>Observation</b>	<b>Verified By Sign /Date</b>
To Stop the In line homogenizer.	Motor shall stop and Homogenizer shall stop rotating.	“OFF” the Recirculation from HMI		
To check steam circulation into the jacket.	Steam shall start flowing into the jacket and pressure and temperature shall be considered.	“ON” the Heating on HMI and set the required temperature and observe the pressure in line		
To check cooling water circulation into the jacket.	Cooling water shall start flowing into the jacket and pressure shall be considered.	“ON” the Cooling on HMI		
To stop the Water (steam and cooling water) supply into the jacket.	Steam and cooling water shall stop flowing into the jacket and pressure shall decrease	“OFF” the heating and cooling one by one by HMI.		
Challenge the opening of safety valve of jacket	The Safety valve shall get open when pressure inside jacket shall increasing just to set point (Maximum set point 3.2 kg/cm <sup>2</sup> )	Set the safety valve 3.0 kg/cm <sup>2</sup> and “ON” the steam supply into jacket by HMI and Heating was “ON” and closed the outlet of steam.		



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<b>Name of System Component</b>	<b>Specified Function</b>	<b>Method Of Verification</b>	<b>Observation</b>	<b>Verified By Sign /Date</b>
To start lobe pump of vessel	Lobe pump shall start transferring the material	“ON” the lobe pump by HMI.		
To stop lobe pump of vessel.	lobe pump shall stop	“OFF” lobe pump by HMI.		
To Check the rotation of spray ball	Rotation of spray ball shall be satisfactory	Connect the water supply to spray ball and “ON” the spray ball in manual mode of HMI.		
Verify the temperature shown at HMI as Present Value	The difference between temperature shown at HMI and actual temperature in tank shall be less than 1 <sup>0</sup> C.	“ON” the heating and Verify the temperature from ambient to 80 <sup>0</sup> C by external Temperature sensors.		
Check for any abnormal sound/noise or vibration during its operation	No abnormal sound/noise or vibration shall be observed during its operation	By Starting the equipment in its optimum operating range as per draft SOP		

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.5.3 Verification of Interlocks**

<b>Function of Component</b>	<b>Acceptance Criteria</b>	<b>Method Of Verification</b>	<b>Observation</b>	<b>Verified By Sign /Date</b>
No Air pressure in air line	Red lamp shall glow and An audio and visual alarm shall display on HMI “NO INCOMING AIR”	Close the compressed air supply in main air line		
Emergency Pressed	Red lamp shall glow and An audio and visual alarm shall display on HMI “EMERGENCY PRESSED”	Press the emergency in machine running condition		
Power tripped	Red lamp shall glow and An audio and visual alarm shall display on HMI “MAIN POWER TRIP”.	By rotating the main power switch to ‘OFF’ position		
Top stirrer shall not rotate when top lid in up position	Red lamp shall glow and An audio and visual alarm shall display on HMI “LID OPEN” and stirrer shall not rotate	Lift up the top lid and “ON” the anchor (Stirrer)		



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Function of Component	Acceptance Criteria	Method Of Verification	Observation	Verified By Sign /Date
Stirrer motor trip in stirrer running condition	Red lamp shall glow and An audio and visual alarm shall display on HMI “MFG STIRRER TRIP” and stirrer shall not rotate	“ON” the stirrer of vessel and Trip the motor of stirrer from control panel.		
In line homogeniser shall not operate/function if there is no chilled water supply	Red lamp shall glow and An audio and visual alarm shall display on HMI “NO HOMOGEN FLOW SWITCH” and In line homogenizer shall stopped	Disconnect the chilled water supply from In line homogenizer.		
Steam supply shall get “OFF” when the temperature shall reach to set temperature and supply shall start when temperature shall go below than set temperature.	Steam supply shall get closed and pressure at jacket shall be “0” and temperature shall not increase further after stabilization again the pressure at jacket and temperature shall increase when steam supply resumes.	Set the temperature and “ON” the Heating by HMI		

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.6 VERIFICATION OF SUPPORTING UTILITIES:**

Utility	Method of verification	Observation	Verified by Sign/ Date
Electricity: 03 Phase, 415 V AC, 50 Hz	By Challenging		
Compressed Air: NLT 6.0 kg/cm <sup>2</sup>	By Challenging		
Steam Supply	Visually/ Challenging		
Cool water Supply	Visually/ Challenging		
Purified water Supply	Visually/ Challenging		

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.7 VERIFICATION OF SAFETY FEATURE**

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

Safety features description	Procedure for verification	Specification	Observation	Verified By Sign/Date
Fully covered all the moving or hazards parts	To prevents the body parts coming with moving or hazards parts	Visually/ Challenging		
Earthing of Electrical control Panel, machine motor, hydraulic system	To avoid accident due to the leakage current	Visually/ Challenging		
Safety Valve	To avoid the accident due to high pressure in the jacket	Visually/ Challenging		
Emergency stop	To stop the machine	Visually/ Challenging		

**Remark:** -----  
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**Reviewed by (Sign/Date)**





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**5.8 VERIFICATION OF STANDARD OPERATING PROCEDURE (SOP)**

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

Sr. No.	SOP Title	SOP Number	Verified By Sign/Date

**Remark:** -----  
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**Reviewed by (Sign/Date)**

**5.9 TRAINING RECORD OF PERSONNEL (S):**

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S. No.	Name of Personnel	Designation	Sign. & Date	Trained By	Remark

**Remark:** -----  
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**Reviewed by (Sign/Date)**

**5.10 LIST OF ANNEXURES:**





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Following deficiency was identified 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)**

**5.12 Abbreviations**



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Following Abbreviations are used in the Operational Qualification of Main Manufacturing Vessel

VFD: Variable Frequency Drive

NA: Not Applicable

RPM: Revolution per Minutes

ID No.: Identification Number



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**6.0 OPERATIONAL 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. Verified that 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 Operational qualification report of Main Manufacturing Vessel have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
<b>REVIEWED BY</b>			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
<b>APPROVED BY</b>			HEAD OPERATION		
			QUALITY ASSURANCE		