



PHARMA DEVILS

**OPERATIONAL QUALIFICATION PROTOCOL
FOR
STORAGE TANK**

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 Operation Qualification protocol of Storage Tank 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		



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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 Storage Tank 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 Storage Tank 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 Storage Tank in ointment area of manufacturing facility at

Once the operational qualification of Storage Tank has been completed successfully, the equipment shall be preceded for the performance qualification procedure.

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.



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- 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.



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3.0 ACCEPTANCE CRITERIA

- 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 RPM of motor 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.



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5.0 OPERATIONAL QUALIFICATION PROCEDURE

5.1 SYSTEM DESCRIPTION:

- | | | | |
|---|-----------------------|---|---|
| 1 | Equipment Name | : | Storage Tank |
| 2 | Supplier/Manufacturer | : | Bectochem Consultants & & Engineers Pvt. Ltd. |
| | Model | : | GMP |
| 3 | Serial no. | : | NA |
| 5 | Location | : | Holding Tank |

The Storage Tank consists of Following Components:

1. Storage Tank comprises of top lid and bottom cone welded with central cylindrical shell.
2. Storage Tank is provided with jacket for maintaining the product temperature.
3. Stirrer entry at the top with the drive for the stirrer is mounted on a hinged plate at the top edge of the Tank. It will be provided with a VFD for speed variation. This assembly is provided with the single cartridge mechanical seal.
4. Storage Tank is designed for steam circulation.
5. Entire Tank is mounted on 4 Nos. leg supports which are fixed.



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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.



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5.3 TEST INSTRUMENT DETAILS

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: -----

Reviewed by (Sign/Date)



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5.4 Verification of Calibrated Component :

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 of the Storage tank.

S.No.	Name of Instrument	Inst. ID. Number	Calibration done on	Calibration valid up to	Certificate number

Checked by Date:

Remarks:-----

Verified By & Date:



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5.5 VERIFICATION OF FUNCTIONAL CHECKS:

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

5.5.1 Verification of functional checks:

TEST PARTICULARS	SPECIFIED FUNCTION	METHOD OF VERIFICATION	OBSERVATION	VERIFIED BY (sign /date)
Vessel Jacket	For steam/cool water circulation purpose	Visually/ Challenging		
Top Entry agitator	For proper mixing	Visually/ Challenging		
Inlets	final product inlet to the vessel and water inlet into jacket	Visually/ Challenging		
Outlets	final product outlet from the vessel and water outlet from jacket	Visually/ Challenging		
Metering Pump	To transfer the final product to tube filling machine	Visually/ Challenging		
Load Cell	For weight verification.	Visually/ Challenging		
Safety Valve Jacket	For safety of the vessel from over pressure	Visually/ Challenging		

Remark: -----

Reviewed by (Sign/Date)



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5.5.2 Verification of operation key functionality of major components:

Name of System Component	Specified Function	Method Of Verification	Observations	Verified By Sign/Date
Switch 'ON' the main power supply	Power flow shall come to the control panel	By rotating the main power switch to 'ON' position		
Control ON/OFF turn selector switch from OFF mode to ON mode	Power comes into control panel and this is indicated by the three lights on the front panel having R Y B lamp indicator.	By rotating the selector switch ON/OFF turn		
Start Ancho of Storage Vessel	stirrer shall start rotating	By Touching the Icon "Storage Vessel Anchor Start" on HMI		
Stop the Anchor of Storage Vessel	stirrer shall stop rotating	By Touching the Icon "Storage Vessel Anchor Stop" on HMI		



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Name of System Component	Specified Function	Method Of Verification	Observations	Verified By Sign/Date
Verify the speed of Stirrer (1-36 RPM)	Speed of the Stirrer shall change as per the set value in HMI.	By Touching the Icon “Storage Vessel Anchor Start” and putting the RPM value (0-36) on HMI. Speed shall increase and, decrease as per set value. Verify at 5, 10, 15, 20, 25, 30 & 36 RPM.		
Start the steam supply into the jacket.	Steam circulation shall start into the jacket and pressure and temperature shall increase in circulation line.	“ON” the heating from HMI		
Start the cooling water supply into the jacket.	Cooling water circulation shall start into the jacket and pressure shall increase in circulation line.	“ON” the cooling from HMI		
To stop the steam & cooling water supply into the jacket	Steam & cooling water circulation shall stop into the jacket and pressure shall decrease in line.	“OFF” the cooling/heating from HMI		



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Name of System Component	Specified Function	Method Of Verification	Observations	Verified By Sign/Date
Verify the temperature shown at HMI as Present Value. [Pre-requisite: IR Temperature Indicator]	The difference between temperatures in vessel shall be less than 1 ⁰ C.	“ON” the heating pump and fill the purified water into vessel and compare the temperature		
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.		
To start the metering pump of storage tank	Metering pump shall start	By touching the icon “Metering pump start” on HMI		
To stop the metering pump of storage tank	Metering pump shall stopped	By touching the icon “Metering pump stop” on HMI		



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Name of System Component	Specified Function	Method Of Verification	Observations	Verified By Sign/Date
Challenge the capacity of vessel and verify the load cell.	<ul style="list-style-type: none"> • Maximum working capacity: 1765 Kg. • Gross Capacity: 1900 Kg. 	Measure the purified water Verify the Maximum working and gross capacity And verify the load cell with purified water.		
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 Machine		

Remark: -----

Reviewed by (Sign/Date)



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5.5.3 VERIFICATION OF SAFETY FEATURES (ALARMS):

TEST PARTICULARS	ACCEPTANCE CRITERIA/FUNCTION	METHOD OF VERIFICATION	OBSERVATION	VERIFIED BY (sign/date)
Stirrer Stopped/tripped	A visual alarm shall display on control panel Yellow lamp "Holding vessel trip" shall glow	Stop/trip the stirrer		
Metering Pump Stopped/tripped	a visual alarm shall display on HMI "Metering Pump trip"	Stop/trip the metering pump.		
Emergency Pressed	A visual alarm shall display on HMI "Emergency Pressed" and equipment operation shall stop.	Pressed the emergency in machine running condition.		
Check the Steam circulation stoppage when the temperature reaches to set temperature and again start of circulation shall when temperature decreases 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 temperature shall go down and steam supply resumes.	Set the temperature and "ON" the Steam circulation.		

Remark: -----

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 ²	By Challenging		
Steam Supply	Visually/ Challenging		
Cool water Supply	Visually/ Challenging		
Purified water Supply	Visually/ Challenging		

Remark: -----

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	FUNCTION	METHOD OF VERIFICATION	OBSERVATION	VERIFIED BY SIGN & DATE
Fully covered all the moving or hazards parts	To prevents the body parts coming in contact with moving or hazards parts	Visually		
Earthing	To avoid accident due to the leakage of current	Visually/ By challenging		

Remark: -----

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 Storage Tank.

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

Remark: -----

Reviewed by (Sign/Date)



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5.9 TRAINING RECORD OF PERSONNEL (S):

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

Remark: -----

Reviewed by (Sign/Date)



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

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)**



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5.12 Abbreviations

Following Abbreviations are used in the Operational Qualification of Storage tank.

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 Storage Tank have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

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