PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL FOR HOLDING VESSEL	PROTOCOL No.:

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 Holding 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:

2.1 OBJECTIVE:

The objective of developing and executing this protocol is to collect sufficient data pertaining to the Holding 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 Holding 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 Holding Vessel in ointment area of manufacturing facility at ……..

Once the operational qualification of Holding Vessel 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.
- 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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2.5 EXECUTION TEAM:

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

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

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

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 ±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

5.1 SYSTEM DESCRIPTION:

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

The Holding Vessel consists of Following Components:

- Jacketed Vessel comprises of top lid and bottom dished end welded with central cylindrical shell.
- It is provided with jacket for circulation of steam.
- Stirrer entry at the top of rating 2 HP, 1420 RPM with the drive for the stirrer is mounted on a hinged plate at the top edge of the vessel. This vessel is provided with a manually operated ball valve as the bottom valve.
- Entire vessel is mounted on 4 Nos. leg supports which are fixed.
- All pipes, pipe fittings and valves in contact with product are of SS 316L with TC connection and silicon gaskets.

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

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)

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 Holding Vessel.

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

Done By & Date:

Remarks:----------

Verified By & Date:

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:

Name of System Component	Specified Function	Method Of Verification	Observation	Verified By Sign /Date
Vessel Jacket	For circulation of Steam into jacket	Visually/ Challenging		
Top Entry agitator	For proper mixing	Visually/ Challenging		
Jacket Inlet and Outlet	For steam inlet into jacket and steam outlet	Visually/ Challenging		
Material Outlet	For material Outlet from vessel	Visually/ Challenging		
Challenge the capacity of vessel	**Minimum Working Capacity:** 10 Kg **Maximum Working Capacity:** 50 Kg **Gross Capacity:** 60 Kg.	With measured quantity of Purified water		
Pneumatically operated valves	Smooth and proper actuation of Pneumatically operated valves	Visually/ Challenging		
Measuring Instruments	Smooth and proper functioning of Measuring Instruments	Visually/ Challenging		

Name of System Component	Specified Function	Method Of Verification	Observation	Verified By Sign /Date
Check for any abnormal sound/noise or vibration during its operation	No abnormal sound/noise or vibration shall be observed	By Starting the Machine		

Remark: ----------

Reviewed by (Sign/Date)

5.5.2 Verification of Operation Key Functionality Of Major Components Of The System:

Name of System Component	Specified Function	Method Of Verification	Observations	Verified By Sign/Date
Switch 'ON' the main power panel supply	Power flows should come up to the main panel	By rotating the main power switch to 'ON' position		
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 (Touch screen HMI)	By rotating the Control ON/OFF turn toggle key		
To start the stirrer of Jacketed Holding Vessel	stirrer shall start	"ON" the stirrer from HMI		
To Stop stirrer of Jacketed Holding Vessel	stirrer shall Stop	"OFF" the stirrer from HMI		
Verify the speed of Stirrer	Stirrer shall Rotate	Verify the speed (60, RPM) by tachometer.		
Check the steam circulation in vessel	Steam circulation shall start and there shall be increase in jacket pressure and vessel temperature	"ON" the heating from HMI		

Name of System Component	Specified Function	Method Of Verification	Observations	Verified By Sign/Date
To stop the steam supply into the jacket.	Steam shall stop flowing into the jacket and pressure shall decrease.	"OFF" the heating from HMI.		
Challenge the opening of safety valve of jacket	The Safety valve shall get open when pressure inside jacket shall increasing to set point (Set point 3.0 kg/cm^2)	Increase the pressure inside jacket at (point 3.2 kg/cm2)		
Verify the temperature shown at HMI as Present Value **[Pre-requisite: IR Temperature Indicator]**	The difference between temperature shown at HMI and actual temperature in tank shall be less than 1^0C.	"ON" the heating and verify the temperature with purified water up to 85^0C and compare the temperature		

Remark: ----------

Reviewed by (Sign/Date)

5.6 VERIFICATION OF SUPPORTING UTILITIES:

UTILITY	METHOD OF VERIFICATION	OBSERVATIONS	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		
Purified water supply	Visually/Challenging		

Remark: ----------

Reviewed by (Sign/Date)

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 vessel motor	To avoid accident due to the leakage current	Visually/challenging		
Vessel's Stirrer Motor trip	Red lamp shall glow and An audio and visual alarm shall display on HMI "MIX VESS STR TRIP"	Trip the motor stirrer of Mix Vessel from control panel in stirrer running condition		

Remark: ----------

Reviewed by (Sign/Date)

5.8 VERIFICATION OF STANDARD OPERATING PROCEDURE (SOP)

The following Standard Operating Procedures were identified as important for effective performance of Holding Vessel.

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

Remark: ----------

Reviewed by (Sign/Date)

5.9 TRAINING RECORD OF PERSONNEL (S):

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

Remark: ----------

Reviewed by (Sign/Date)

5.10 LIST OF ANNEXURES:

Annexure No.	Document Title

Remarks (if any)**:** ----------

Done By & Date: **Verified By & Date:**

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)

5.12 Abbreviations

Following Abbreviations are used in the Operational Qualification of Holding Vessel

NA: Not Applicable

RPM: Revolution per Minutes

ID No.: Identification Number

6.0 OPERATIONAL QUALIFICATION FINAL REPORT:

6.1 SUMMARY:

6.2 CONCLUSION:

Prepared By
Sign/Date

Checked By
Sign/Date

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 Holding 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
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		