PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL FOR WATER PHASE VESSEL	PROTOCOL No.:

S.No.	ITEM DESCRIPTION	PAGE No.
1.0	**PROTOCOL APPROVAL**	2
2.0	**OVERVIEW:**	3
2.1	Objective	3
2.2	Purpose	3
2.3	Scope	3
2.4	Responsibility	3-4
2.5	Execution Team	5
3.0	**ACCEPTANCE CRITERIA**	6
4.0	**REVALIDATION CRITERIA**	6
5.0	**OPERATIONAL QUALIFICATION PROCEDURE**	7
5.1	Equipment Description	7
5.2	Instruction for Filling the Checklist	8
5.3	Test Instrument Details	9
5.4	Verification of Calibrated component	10
5.5	Verification of functional checks	11-18
5.6	Verification of supporting utilities	19
5.7	Verification of safety feature	20-22
5.8	Verification of Standard Operating Procedure	23
5.9	Training Record Of Personnel (S)	23
5.10	List of Annexures	24
5.11	Deficiency And Corrective Action(s) Report(s)	25
5.12	Abbreviations	26
6. 0	**OPERATIONAL QUALIFICATION FINAL REPORT**	27
6.1	Summary	27
6.2	Conclusion	27
6.3	Final report approval	28

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 Water Phase 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 Water Phase 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 Water Phase 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 Water Phase Vessel in ointment area of manufacturing facility at ……...

Once the operational qualification of Water Phase 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.

.

2.5 EXECUTION TEAM:

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

Execution team is responsible for the execution of Operational of Water Phase 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	:	Water Phase Vessel
2	Supplier/Manufacturer	:	Bectochem Consultants & & Engineers Pvt. Ltd.
	Model	:	NA
3	Serial no.	:	NA
5	Location	:	Manufacturing

The Water Phase Vessel consists of Following Components:

- Water Phase vessel comprises of top dish and bottom dished end welded with central cylindrical shell.
- Water Phase Vessel is provided with jacket for circulation of steam and cooling water.
- Bottom entry stirrer of rating 2 HP, 935 RPM is provided with special design base plate support. The drive for the stirrer is mounted on hinged plate at the top edge of the vessel. This vessel is provided with a conical filter at the bottom outlet valve.
- Entire vessel is mounted on 4 Nos. leg supports which are fixed.
- All pipes fitting and valves in contact with product are SS 316L with TC connection and silicon gasket.

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 Water Phase 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 steam circulation purpose	Visually/ Challenging		
Bottom Entry stirrer	For proper mixing	Visually/ Challenging		
Spray Ball	For cleaning the vessel.	Visually/ Challenging		
Inlets	• For steam inlet to the Jacket • Vacuum and Product inlet	Visually/ Challenging		
Outlets	water and product outgoing from the jackets and vessel	Visually/ Challenging		
Safety Valve of Jacket	For safety of the vessel from over pressure	Visually/ Challenging		
Challenge the Maximum Working capacity and Gross capacity of vessel	**Maximum Working Capacity** : 1000 Kg **Gross Capacity**: 1260 Kg	Capacity verification was executed with measured Quantity of Purified Water.		
Pneumatic valves	Smooth & proper actuation of Pneumatically operated valves	Visually/ Challenging		
Measuring Instruments	Smooth & proper functioning of Measuring Instruments	Visually/ Challenging		

NAME OF SYSTEM COMPONENT	SPECIFIED FUNCTION	METHOD OF VERIFICATION	OBSERVATION	VERIFIED BY (Sign/Date)
Leakage Test	There should not be any leakage from vessel	Fill the vessel with water. Close all nozzles to vessel (Inlet, outlet, drain etc.). Check leakage from vessel.		

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

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL FOR WATER PHASE VESSEL	PROTOCOL No.:

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 (Single level Password Protected Touch screen HMI)	By rotating the Control ON/OFF turn toggle key		
Vessel lamp	Lamp in vessel shall get "ON" and "OFF"	"ON" and "OFF" the lamp on touch screen HMI panel.		
Start stirrer of Water phase vessel	Motor shall get start and stirrer shall start rotating	"ON" the stirrer on touch screen HMI panel.		
Stop the stirrer of Water phase vessel	Motor shall get stop and stirrer shall stop rotating	"OFF" the stirrer on touch screen HMI panel.		
Verify the speed of Stirrer (935 RPM)	Stirrer shall Rotate	Verify the speed by tachometer.		

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL FOR WATER PHASE VESSEL	PROTOCOL No.:

NAME OF SYSTEM COMPONENT	SPECIFIED FUNCTION	METHOD OF VERIFICATION	OBSERVATIONS	VERIFIED BY SIGN/DATE
Observe the stirrer of water phase vessel for smooth operation	Smooth running/operation of stirrer shall be observed	By "ON" the stirrer form 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		
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 1^0C.	"ON" the Heating on HMI and pour the purified water into vessel and compare the temperature from ambient to 80^0 C by external Temperature measuring device with HMI Value, Record the detail in attached Annexure		

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL FOR WATER PHASE VESSEL	PROTOCOL No.:

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 into the jacket and pressure and temperature shall be accordingly in line and pressure shall decrease.	"OFF" the heating by HMI		
Challenge the opening of safety valve of jacket	The Safety valve shall get open when pressure inside jacket shall increasing to set point	By increasing the pressure to set point inside the jacket.		
Check the suction of liquid items in water phase vessel	The dispensed liquid shall get completely sucked in vessel	By creating the vacuum in water phase vessel		
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		
Check for any abnormal sound/noise or vibration during its operation	No abnormal sound/noise or vibration shall be observed	By Starting the equipment in its optimum operating range as per SOP.		

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		
Chilled water	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	ACCEPTANCE CRITERIA/FUNCTION	METHOD OF VERIFICATION	OBSERVATION	VERIFIED BY (SIGN/DATE)
Heating pump tripped for steam tank	Red lamp shall glow and An audio and visual alarm shall display on HMI "HEATING PUMP TRIPP"	Trip pump of steam tank		
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"	Pressed the emergency in machine running mode		
Power tripped	Red lamp shall glow and audio and visual alarm shall display on HMI "PHASE LOSS".	By rotating the main power switch to 'OFF' position.		
Stirrer tripped	Red lamp shall glow and audio and visual alarm shall display on HMI "WATER STIRRER TRIP".	Trip the motor of stirrer from control panel.		
Stirrer stopped in between set time	Red lamp shall glow and An audio and visual alarm shall display on HMI "NO WAT FLOW SWITCH"	Close the supply of chilled water in flow switch of stirrer motor		

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 Heating by HMI		

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 Water Phase 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 Main Water Phase 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 Water Phase 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		