



PHARMA DEVILS

**INSTALLATION QUALIFICATION PROTOCOL
FOR
WATER PHASE 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 Installation 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		
			QUALITY ASSURANCE		
REVIEWED BY			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		

2.0 OVERVIEW:

2.1 OBJECTIVE:



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

The Qualification of Water Phase 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 Water Phase 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 Water Phase Vessel in ointment area of the manufacturing facility at & the subsequent documentation.

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 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.



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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 Water Phase Vessel shall meet the system description given in design qualification.
- 3.2 The Water Phase 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	:	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 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.



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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
Water Phase Vessel	Make	Bectochem Consultants & Engineers Pvt. Ltd.	Visually on name plate		
	Gross Capacity	1260 Liters	Visually on name plate		
	Working Capacity	1000 Liters	Visually on name plate		
Motor	Make	Bharat Bijlee	Visually / Physically		
	Sr. No.	To be recorded	Visually / Physically		
	Spec.	2 HP, 960 RPM, NON-FLP	Visually / Physically		
Main Shell	Make	BCEPL	Physically/ Technical Specification		
	Size	5 Thk	Physically/ Technical Specification		
Top Dish End	Make	BCEPL	Physically/ Technical Specification		
	Size	5 Thk	Physically/ Technical Specification		



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System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Make				
Bottom Dish End	Make	BCEPL	Physically/ Technical Specification		
	Size	5 Thk	Physically/ Technical Specification		
Jacket Shell	Make	BCEPL	Physically/ Technical Specification		
	Size	5 Thk	Physically/ Technical Specification		
Jacket Dish End	Make	BCEPL	Physically/ Technical Specification		
	Size	5 Thk	Physically/ Technical Specification		
Insulation Shell/Dish	Make	BCEPL	Physically/ Technical Specification		
	Size	5 Thk	Physically/ Technical Specification		
Leg Pipe	Make	BCEPL	Physically/ Technical Specification		
	Size	80 NB X SCH. 40	Physically/ Technical Specification		
Baffle Plate	Make	BCEPL	Physically/ Technical Specification		
	Size	8 mm	Physically/ Technical Specification		



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System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Propeller Shaft	Make	BCEPL	Physically/ Technical Specification		
	Size	Ø 60	Physically/ Technical Specification		
Impeller Sweep	Make	BCEPL	Physically/ Technical Specification		
	Size	Ø 175 X 5 Thk	Physically/ Technical Specification		
Base Plate	Make	BCEPL	Physically/ Technical Specification		
	Size	20 mm	Physically/ Technical Specification		
Sensor PT 100	Make	Eureka	Visually / Physically		
	Size	½" BSP	Physically/ Technical Specification		
Compound gauge	Make	Baumer	Physically/ Technical Specification		
	Spec.	4", -1 to 5 kg/cm ²	Physically/ Technical Specification		
Pressure Gauge	Make	Waaree	Visually / Physically		
	Spec.	0-7 kg/cm ²	Visually / Physically		
	Qty.	01 No.	Visually / Physically		



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System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Nozzle Schedule					
N1	Location	Manhole	Visually / Physically		
	Size	Ø 450 X 5 Thk	Physically/ Technical Specification		
N2	Location	Bottom Inlet	Visually / Physically		
	Size	38 OD X 14 SWG	Physically/ Technical Specification		
N3	Location	Bottom Outlet	Visually / Physically		
	Size	2"	Physically/ Technical Specification		
N4	Location	Vacuum Manifold	Visually / Physically		
	Size	38 OD X 14 SWG	Physically/ Technical Specification		
N5	Location	CIP Spray Nozzle	Visually / Physically		
	Size	75/ 38 OD X 14 SWG 75 OD X 14 SWG	Physically/ Technical Specification		
N6	Location	Steam Inlet/ Cold Water Outlet	Visually / Physically		
	Size	25 NB X SCH 40	Physically/ Technical Specification		



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System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
	Location				
N7	Location	Steam Outlet/ Cold Water Inlet	Visually / Physically		
	Size	25 NB X SCH 40	Physically/ Technical Specification		
N8	Location	Jacket Vent	Visually / Physically		
	Size	½" NB X SCH 40	Physically/ Technical Specification		
N9	Location	Jacket Drain	Visually / Physically		
	Size	½" NB X SCH 40	Physically/ Technical Specification		
N10	Location	Thermowell	Visually / Physically		
	Size	15 NB X SCH 10	Physically/ Technical Specification		
N11	Location	Spray Nozzle	Visually / Physically		
	Size	38 OD X 14 SWG	Physically/ Technical Specification		
N12	Location	Light Glass	Visually / Physically		
	Size	Ø 100	Physically/ Technical Specification		
N13	Location	Sight Glass	Visually / Physically		
	Size	Ø 100	Physically/ Technical Specification		

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 Dish End	SS 316 L	By Molybdenum Kit/ Test Certificate		
Propeller Shaft	SS 316	By Molybdenum Kit/ Test Certificate		
Baffle Plate	SS 316 L	By Molybdenum Kit/ Test Certificate		
Impeller Sweep	SS 316 L	By Molybdenum Kit/ Test Certificate		
Jacket Shell	SS 304	By Molybdenum Kit/ Test Certificate		
Jacket Dish End	SS 304	By Molybdenum Kit/ Test Certificate		
Insulation Shell/ Dish	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		
3.	Purified Water Supply	Visually		

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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5.9 IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP)

The following Standard Operating Procedures were identified as important for effective performance of Water Phase Vessel operation.

S.No.	SOP Title	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 Water Phase Vessel.

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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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 Water Phase 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 Water Phase 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		