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 Installation 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 installation qualification requirements and acceptance criteria for the Holding Vessel. Successful completion of these installation qualification requirements will provide assurance that the Holding Vessel was installed as required in the manufacturing area.

The Qualification of Holding 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 Holding 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 Holding Vessel in ointment area of the manufacturing facility at ……..

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.

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 installation 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 installed satisfactorily.

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

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 ACCEPTANCE CRITERIA:

3.1 The Holding Vessel shall meet the system description given in design qualification.

3.2 The Holding 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

5.0 INSTALLATION QUALIFICATION PROCEDURE:

5.1	SYSTEM DESCRIPTION:		
1	Equipment Name	:	Holding Vessel
2	Supplier/Manufacturer	:	Bectochem Consultants & & Engineers Pvt. Ltd.
	Model	:	GMP Compliant
3	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 and cooling water.
- Stirrer entry at the top with the drive for the stirrer is mounted on a hinged plate at the top edge of the vessel. It will be provided with a VFD for speed variation.
- 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 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.

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		

S.No.	Statement	Method Of Verification	Actual Observation	Checked By Sign/Date
11	Equipment/system identification no. Is visible	Physically		

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

Reviewed by (Sign/Date)

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
Vessel Design	Make	Bectochem Consultants & Engineers Pvt. Ltd.	Visually/ Technical Specification		
	Gross Capacity	60 Liters	Visually/ Technical Specification		
	Working Capacity	50 Liters	Visually/ Technical Specification		
Motor	Make	HMM	Visually / Physically		
	Sr. No.	To be recorded	Visually / Physically		
	Spec.	2 HP, 1420 RPM, NON-FLP, Frame- 90L	Visually / Physically		
Main Shell	Make	BCEPL	Physically/ Technical Specification		
	Size	3 Thk	Physically/ Technical Specification		
Top Lid	Make	BCEPL	Physically/ Technical Specification		
	Size	3 Thk	Physically/ Technical Specification		

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

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Bottom Dish End	Make	BCEPL	Physically/ Technical Specification		
	Size	3 Thk	Physically/ Technical Specification		
Gear Box	Make	Bonfiglioli	Visually / Physically		
	Type	……..	Visually / Physically		
	Ratio	21.15:1	Physically/ Technical Specification		
Jacket Shell	Make	BCEPL	Physically/ Technical Specification		
	Size	3 Thk	Physically/ Technical Specification		
Jacket Dish End	Make	BCEPL	Physically/ Technical Specification		
	Size	3 Thk	Physically/ Technical Specification		
Insulation Shell/Dish	Make	BCEPL	Physically/ Technical Specification		
	Size	2 Thk	Physically/ Technical Specification		
Leg Pipe	Make	BCEPL	Physically/ Technical Specification		
	Size	50 NB X SCH. 40	Physically/ Technical Specification		

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

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Anchor Shaft	Make	BCEPL	Physically/ Technical Specification		
	Size	Ø 50	Physically/ Technical Specification		
Anchor Sweep	Make	BCEPL	Physically/ Technical Specification		
	Size	Ø 340 X 4 Thk	Physically/ Technical Specification		
Paddle Sweep	Make	BCEPL	Physically/ Technical Specification		
	Size	5 Thk	Physically/ Technical Specification		
Base Plate	Make	BCEPL	Physically/ Technical Specification		
	Size	8 mm	Physically/ Technical Specification		
Sensor PT 100	Make	Eureka	Visually / Physically		
	Size	½" BSP	Visually / Physically		
	Qty.	01 No.	Visually		
Pressure Gauge with Safety Valve & Needle Valve	Make	Baumer	Visually / Physically		
	Spec.	½" Pressure Gauge, Safety Valve & Needle Valve	Visually / Physically		
	Qty.	01 Set	Visually		

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

System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign/Date
Nozzle Schedule					
N1	Location	Jacket Drain	Visually / Physically		
	Size	1/2” NB x SCH 40	Physically/ Technical Specification		
N2	Location	Water Outlet	Visually / Physically		
	Size	1” NB x SCH 40	Physically/ Technical Specification		
N3	Location	Water Inlet	Visually / Physically		
	Size	1” NB X SCH 40	Physically/ Technical Specification		
N4	Location	Jacket Vent	Visually / Physically		
	Size	15 NB X SCH 40	Physically/ Technical Specification		
N5	Location	Thermowell	Visually / Physically		
	Size	15 NB X SCH 10	Physically/ Technical Specification		
N6	Location	Bottom Outlet	Visually / Physically		
	Size	1”	Physically/ Technical Specification		

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

Reviewed by (Sign/Date)

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 Lid	SS 316 L	By Molybdenum Kit/ Test Certificate		
Bottom Dish End	SS 316 L	By Molybdenum Kit/ Test Certificate		
Anchor Shaft	SS 316	By Molybdenum Kit/ Test Certificate		
Anchor Sweep	SS 316 L	By Molybdenum Kit/ Test Certificate		
Paddle 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		
Base Plate	SS 304	By Molybdenum Kit/ Test Certificate		
Leg Pipe	SS 304	By Molybdenum Kit/ Test Certificate		

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

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Reviewed by (Sign/Date)

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		

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

Reviewed by (Sign/Date)

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)

5.8 IDENTIFICATION OF COMPONENT TO BE CALIBRATED

Name of Components	Range	Make	ID	Location	Identified By Sign/Date

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

Reviewed by (Sign/Date)

5.9 IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP)

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

S.No.	SOP Title	Verified By Sign/ Date

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

Reviewed by (Sign/Date)

5.10 VERIFICATION OF DRAWING AND DOCUMENTS:

Following documents are reviewed and attached as listed below:

S.No.	Drawing And Document Detail	Verified By Sign/Date

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

Reviewed by (Sign/Date)

5.11 ABBREVIATIONS

Following Abbreviations are used in the Installation Qualification protocol of Double Head Tube Filling Machine.

MOC : Material of construction

RPM : Rotation per minute

/ : Per

V : Volts

HZ : Hertz

HP : Horse Power

kw : Kilo watt

mm : Millimeter

°C : Degree Centigrade

FLP : Flame Proof

Spec. : Specification

Qty. : Quantity

ltrs. : Liters

Thk : Thick

BCEPL: Bectochem Consultants & Engineers Pvt. Ltd.

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)

5.13 Annexure (S)

Annexure No.	Details Of Annexure

Remarks (if any)**:**

_____

_____

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

6.0 INSTALLATION 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. 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 Holding 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 Holding 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		