PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR COATING SOLUTION 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 signatories.

This Installation Qualification protocol of stirrer has been reviewed and approved by the following signatories:

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 stirrer and define the qualification requirements and acceptance criteria for the unit. Successful completion of these qualification requirements will provide assurance that the stirrer was installed as required in granulation area.

2.2 PURPOSE:

The purpose of this protocol is to establish documentary evidence to ensure that the solution stirrer 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 Installation Qualification of stirrer in Solution Preparation.

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 stirrer shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the stirrer is installed satisfactorily.

Execution team is responsible for the execution of installation qualification of stirrer and Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 ACCETANCE CRITERIA:

3.1 The equipment shall fulfill all the selection criteria and its individual application.

3.2 It shall be complying to all the designed specifications.

3.3 The Material Of Construction (MOC) shall be complying to the specification.

3.4 All supporting utilities of specified capacities are to be near the place of installation

3.5 All the related drawing and documents shall be checked and complied for availability and authenticity.

3.6 All Standard Operating Procedure to be identified.

3.7 All the safety feature and utility to be identified.

4.0 REVALIDATION CRITERIA:

The machine has to be revalidated if

- There are any major changes, which affect the performance of the equipment.
- After major breakdown maintenance is carried out.
- As per revalidation date and schedule

5.0 INSTALLATION QUALIFICATION PROCEDURE

5.1 EQUIPMENT DESCRIPTION:

Equipment Name	:	Coating solution vessel
Supplier / Manufacturer	:	Klassik industries
Overall Dimension		800(W) X 800(L) X 2770 (H)
Model	:	GMP
Serial No.	:	NA
Service it offers	:	Solution preparation in coating Area
Location	:	Solution Preparation

Process Equipment Description

The coating solution Vessel is single drive unit. It consist S.S. Cylindrical shaped Body With dished end Bottom. With rotating agitator shaft, is provided with a impeller opening at one top end with 3 Nos of baffle arrangement for mixing purpose and discharge to be done by at other end through ball valve.

Coating solution Vessel Units are stand-along with SS Leg. The Discharge of the Vessel is trough manual operated ball Valve. Agitator Shaft directly coupled with motor through coupling.
The controls are through an electric panel with push button actuators and timer controls.

Solution preparation stirrer comprises of following components.

1.0 SHAFT

SS 316 Shaft is provided to stirring of the solution.

2.0 MOTOR

2 HP motor is provided to rotate the shaft at defined.

3.0 SUPPORS

SS leg supports are provided.

4.0 OPERATING PANEL

To operate the stirrer through operating panel with the VFD controlling

5.2 Salient Features

- The equipment is designed with good consideration on Environment for safe, pure and effective product manufacturing.
- The fasteners are of SS which is compatible for corrective Environment
- The bottom stand are provided as per cGMP criteria
- Motor and bearing housing are covered with SS perforated sheet for operator safety
- Proper earthing is provided for safety of operator and equipment.
- Control panel is provided to control the RPM through VFD.

5.3 INSTRUCTION FOR FILLING THE CHECKLIST

5.3.1 In case of the compliance of the test use the word ‘Complies’ otherwise use ‘Does not comply‘ to indicate non-compliance.

5.3.2 For identification of the components of the equipment and utilities use the word ‘’yes’’ to show its presence and use ‘No’ to indicate the absence of the identity

5.3.3 Give the detailed information in the summary and conclusion part of the Installation Qualification report.

5.3.4 Whichever column is blank or not used ‘NA’ shall be used.

5.4 INSTALLATION CHECKLIST:

Installation checklist is as follows:

S.No.	STATEMENT	OBSERVATION	CHECKED BY SIGN /DATE
1.	Verify that the "As Built" drawing is complete and represents the design concept.		
2.	Verify that major components are securely anchored and shock proof.		
3.	Verify that there is no observable physical damage.		
4.	Verify that there is sufficient room provided for servicing.		
5.	Verify that all piping and electrical connections are done according to the drawings.		
6.	All access ports are examined and cleared of any debris.		
7.	Safe electrical connections.		
8.	Equipment identification nameplate visible.		
9.	Units installed on foundation are secure in place as per manufacturer's recommendations.		

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

Reviewed by (Sign/Date)

5.5 IDENTIFICATION OF MAJOR COMPONENTS:

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

Equipments Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
Equipment Description	Name	Coating solution vessel	Verified with name plate/ Technical Certificate		
	specification	Flame proof construction	Physically/ Technical specification		
	Capacity	300 liter	Physically/ Technical specification		
	Surface finish	Internal mirror 240 Grit	Physically/ Technical Certificate		
Main Motor	Type	TEFC, Flame proof, squirrel cage, 3 phase Induction motor	Physically/ Technical Certificate		
	Make	HMM	Verified with name plate		
	Capacity	2 HP, 3 Amp.	Verified with name plate		
	RPM	1420	Physically/ Technical Certificate		
	Sr. No.	To be recorded	Physically		
VFD for Main Motor	Make	Delta	Physically		
	Model	VFD015M43B	Physically/ Technical		

			Certificate		
Cycle Timer	Make	Selec	Physically		
	Model	XT 546	Physically/ Technical Certificate		
	Sr. No.	To be recorded	Physically		
Relay	Make	PLA	Physically		
	Model	3 C/O MPC 240 A-5	Physically/ Technical Certificate		
Selector Switch	Make	Salzar	Physically		
Accessories	Phase indicator R, Y & B and Motor ON indicator , Start/Stop push button, Potentio meter,		Physically		

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

Reviewed by (Sign/Date)

5.6 VERIFICATION OF MATERIAL OF CONSTRUCTION: should be verified by test certificates of respective material apart from that SS material should be verified by molybdenum kit in absence of test certificate.

Name of Components	Material of Construction	Method of Verification	Observation	Checked By Sign/Date
Coating Vessel	SS316	Molybdenum Kit/ Technical Certificate		
Top Lid	SS316	Molybdenum Kit/ Technical Certificate		
Agitator Shaft	SS316	Molybdenum Kit/ Technical Certificate		
Control panel	SS304	Molybdenum Kit/ Technical Certificate		
Leg	SS304	Molybdenum Kit/ Technical Certificate		

* Test certificate to be verify and attached to protocol.

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

Reviewed by (Sign/Date)

5.7 IDENTIFICATION OF SUPPORTING UTILITIES:

S.No.	Utility	Method of Verification	Observation	Checked By Sign/Date
1.	**Electricity**: 440 V A.C 3 phase, 50 Hz	Physically		

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

Reviewed by (Sign/Date)

5.8 IDENTIFICATION OF SAFETY FEATURES:

Identify and record the safety features (if any) and their function in following tables :

Safety Features Description	Function	Method of Verification	Observation	Checked By Sign/ Date
1. Earthing	Earthling to be provide to avoid the electric shock	Physically		
2. Power Failure	If main motor is overloaded to draw more current then the limit, the current will trip with help of MCB.	Physically		

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 Stirrer

S.No.	SOP Title	Identified By

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

Reviewed by (Sign/Date)

5.10 IDENTIFICATION OF COMPONENT TO BE CALIBRATED:

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

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

Reviewed by (Sign/Date)

5.11 VERIFICATION OF DRAWING AND DOCUMENTS:

Following documents are reviewed and attached as listed below:

S.No.	DRAWING AND DOCUMENT DETAIL	Checked by (Sign/Date)

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

Reviewed by (Sign/Date)

5.12 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)

5.13 Annexures:

Annexure No.	Title of Annexure

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

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

6.0 INSTALLATION QUALIFICATION FINAL REPORT:

All the IQ data sheets and discrepancy report shall be reviewed by validation team to prepare summary report. The summary of IQ shall be used to draw conclusion for approval of installation qualification 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.

Signature in the block below indicate that all items in this qualification report of stirrer have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

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