



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
COATING SOLUTION VESSEL**

**PROTOCOL No.:**

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**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 coating solution vessel has been reviewed and approved by the following Persons

<b>FUNCTION</b>	<b>NAME</b>	<b>DESIGNATION</b>	<b>DEPARTMENT</b>	<b>SIGNATURE</b>	<b>DATE</b>
PREPARED BY			QUALITY ASSURANCE		
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		



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**2.0 OVERVIEW:**

**2.1 OBJECTIVE:**

The objective of developing and executing this protocol is to collect sufficient data pertaining to the coating solution 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, are the same at utmost transparency.

**2.2 PURPOSE:**

The purpose of this protocol is to establish documentary evidence to ensure that the coating solution 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 coating solution vessel in Solution Preparation.

Once the operational qualification of coating solution vessel has been completed successfully, the equipment shall be preceded for the routine use.

**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



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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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**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  $\pm 5\%$  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.



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**5.0 OPERATIONAL 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 I

**Process Equipment Description**

The purpose of the coating solution vessel is to stirring the solution into the granulation area. The motor is provided to control and revolution of the RPM also VFD provided to the coating solution vessel. and stir the solution by adjusting the RPM on control panel.

**Coating solution vessel comprises of following components:**

1. Shaft
2. Coupling
3. Motor
4. Support stand
5. Operating panel



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**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 Verification of Calibrated component :**









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**5.5 VERIFICATION OF FUNCTIONAL CHECKS:**

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

**5.5 Verification of functionality major component**

<b>Name of System Component</b>	<b>Specified Function</b>	<b>Method of Verification</b>	<b>Observation</b>	<b>Verified By Sign/Date</b>
Shaft	To rotate the impeller	Physically		
Impeller	To stir the material	Physically		
Coupling	To hold the shaft	Physically		
Motor	For revolution of coating solution	By challenging		
Base stand	To hold the coating solution vessel	Physically		
Potentiometer	To set the RPM	By challenging		
<b>Verification of operation key functionality</b>				
Main panels main Switch ON	<b>R,Y,B</b> indicating lamp on main panel glows	Physically		
Process Timer & Indicator	To set & indicate the process time	Physically		
Control OFF/ON Switch on control panel Switched ON	Control ON indicating lamp will Blow	Physically		
Set the different RPM of coating solution vessel and observe	50 RPM 100 RPM 200 RPM 700 RPM 1420 RPM	By challenging with tachometer	----- RPM ----- RPM ----- RPM ----- RPM ----- RPM	



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**PROTOCOL No.:**

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.6 VERIFICATION OF SUPPORTING UTILITIES:**

<b>Utility</b>	<b>Method of Verification</b>	<b>Observation</b>	<b>Verified By Sign/Date</b>
<b>Electricity:</b> Single phase, 415V , 50H supply with neutral and proper earthing	By challenging with clamp meter		

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.7 VERIFICATION OF SAFETY FEATURE:**

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

<b>Safety Features Description</b>	<b>Function</b>	<b>Observation</b>	<b>Verified By Sign/Date</b>
Earthing	To avoid electrical shocks due to leakage current.		
Emergency stop	To stop machine immediately in case of emergency		
FLP Motor	For safety for use in hazardous area		

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**5.8 VERIFICATION OF STANDARD OPERATING PROCEDURE (SOP):**

The following Standard Operating Procedures were identified as important for effective performance of coating solution vessel.

<b>S.No.</b>	<b>SOP Title</b>	<b>SOP Number</b>	<b>Verified By (Sign/Date)</b>

**Remark:** -----  
-----  
-----

**Reviewed by (Sign/Date)**



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**5.9 TRAINING RECORD OF PERSONNEL (S):**

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

**Remark:** -----  
-----  
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**Reviewed by (Sign/Date)**







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**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)**



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**6.0 OPERATIONAL 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. 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 coating solution vessel have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

<b>FUNCTION</b>	<b>NAME</b>	<b>DESIGNATION</b>	<b>DEPARTMENT</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>REVIEWED BY</b>			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
<b>APPROVED BY</b>			HEAD OPERATION		
			QUALITY ASSURANCE		