



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION PROTOCOL CUM  
REPORT  
FOR  
SUPER MILL (CO-MILL)**

**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 Super Mill 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 Super Mill, define the qualification requirements, acceptance criteria for the machine and to prove that each operation proceeds as per design specification and the tolerances prescribed in the document.

**2.2 PURPOSE:**

The purpose of this protocol is to establish documentary evidence to ensure that the Super Mill 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 Super Mill (Co-Mill) in Granulation area of production cepha oral manufacturing facility.

Once the operational qualification of Super Mill is completed successfully, the equipment shall be preceded for 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 as follows:**

- 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



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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 SOP's for the equipment to be verified and checked.
- 3.3 Training is imparted to all the concerned personnel.
- 3.4 All the functionality of equipment components to be checked.
- 3.5 The RPM of motor should be in the range of  $\pm 5\%$ .

**4.0 REQUALIFICATION CRITERIA;**

The machine shall be requalified 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 that affects the performance of equipment.
- As per requalification date and schedule.



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**5.0 OPERATIONAL QUALIFICATION PROCEDURE:**

**5.1 EQUIPMENT DESCRIPTION:**

Equipment Name	:	Super Mill
Supplier / Manufacturer	:	Kevin Process Technologies Pvt Ltd.
Serial No.	:	
Location	:	Granulation
Capacity	:	300 kg/hr(depends on product characteristics and screen size).

**Process Equipment Description:**

The Super Mill is designed for size reduction with low heat and low noise.

Materials to be processed enters the top of Super mill through the pneumatic conveying system and flows into the conical screen chamber, the rotating impeller imparts a vortex flow pattern to the in feed material with centrifugal acceleration forcing particulates to the screen surface. Here particles size are reduced and discharge through the screen openings.

**The major components of the Super Mill are:**

- Charging hopper
- Discharge Hopper
- Discharge Shroud
- Drive Arrangement
- Power Panel with operating Panel

**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.



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**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 operation of Super Mill.

S.No.	Name of Instrument	Inst. ID. Number	Calibration done on	Calibration Due date	Certificate Number

**Checked by Date:**

**Remark:**

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**Reviewed by (Sign/Date)**





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**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 Super Mill.

S.No.	Name of Instrument	Inst. ID. Number	Location	Calibration done on	Calibration valid up to	Certificate number

**Remarks:**

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**Done By & Date:**

**Verified By & Date:**



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**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 for major components:**

<b>Name of System Component</b>	<b>Specified Function</b>	<b>Method of Verification</b>	<b>Observation</b>	<b>Verified By Sign/Date</b>
Inlet Hopper	Provided for transfer of granules to milling section.	Physically by challenging.		
Discharge Hopper	Provided for discharge of granules.	Physically by challenging.		
Motor	Rotates driving assembly.	Physically by challenging.		
Castor Wheel	For movement of machine.	Physically by challenging.		
Screen	For screening of granules.	Physically by challenging.		



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<b>Name of System Component</b>	<b>Specified Function</b>	<b>Method of Verification</b>	<b>Observation</b>	<b>Verified By Sign/Date</b>
Control panel with operating panel consisting of:  1)Start and stop push buttons.  2)Increase and decrease push buttons  3)Emergency red headed mushroom push button.  4)RPM meter.	Buttons and indicators provided should be functional.  To start and stop the impeller rotation.  To increase or decrease the RPM of impeller.  To stop the machine during emergency.  To display the actual RPM of impeller.	Physically by challenging.		

**Remark:** -----

**Reviewed by (Sign/Date)**



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**5.5.2 Verification of operational keys functionality**

<b>Name of System Component</b>	<b>Specified Function</b>	<b>Method of Verification</b>	<b>Observation</b>	<b>Verified By Sign/Date</b>
Start and stop push buttons.	Impeller RPM should start and stop	Physically by challenging.		
Increase and decrease push buttons	To increase or decrease the impeller speed.	Physically by challenging. Set various RPM as mentioned below and compare the actual RPM by means of tachometer and record in the column as mentioned below:		
		Set RPM	Actual RPM (Tachometer)	
		300		
		1000		
		1440		
Emergency red headed mushroom push button.	To stop the machine during emergency.	Physically by challenging.		
RPM meter	To display the actual RPM of impeller.	Physically by challenging.		
Main ON/OFF selector switch	To start or stop the main power supply.	Physically by challenging.		

**Remark:**

**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>
Electricity: 3 phase, 415V AC, 50Hz supply with neutral and proper earthing.	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>Method of Verification</b>	<b>Observation</b>	<b>Checked By Sign/ Date</b>
Earthing	To avoid electrical shocks due to leakage of current.	Physically by challenging.		
Gasket	To prevent dusting while operation	Physically by challenging.		
Motor housing	To guard moving part	Physically by challenging.		
Impeller motor overload	Impeller motor will not run under heavy load.	Physically by challenging.		
Emergency stop	To stop machine incase of emergency.	Physically by challenging.		
Shroud and Hopper interlock	Impeller will not run if the shroud and hopper are opened.	Physically by challenging.		
Guard interlock	Impeller will not run if the guards are opened.	Physically by challenging.		

**Remark:** -----

**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 Super Mill.

S.No.	SOP Title	SOP Number	Verified By Sign/Date

**Remark:**

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**Reviewed by (Sign/Date)**

**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(if applicable) are documented, approved and attached to this protocol. Signatures in the block below indicates that all items in this Operational qualification report of Super Mill have been reviewed and found to be acceptable, all variations or discrepancies(if applicable) 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		