



PHARMA DEVILS

**INSTALLATION 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 signatories:

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

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
PREPARED BY			QUALITY ASSURANCE		
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
APPROVED BY			PRODUCTION		
			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 and acceptance criteria for the unit. Successful completion of these qualification requirements will provide assurance that the Super Mill was installed as required in Granulation-.

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:

This protocol is applicable to installation of Super Mill (Co-Mill) in Granulation.

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.



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3.0 ACCEPTANCE CRITERIA:

- 3.1 The Super Mill shall meet the system description given in design specification.
- 3.2 The Super Mill 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 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.



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5.0 INSTALLATION 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



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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 the purchase order copy and PO no. Shall be written in observation column	Physically		
2.	Verify that the "As Built" drawing is complete and represents the design concept.	Physically		
3.	Verify that major components are securely anchored and shock proof.	Physically		
4.	Verify that there is sufficient room provided for servicing.	Physically		
5.	Verify that all piping and electrical connections are done according to the drawings.	Physically		
6.	All access ports are examined and cleared of any debris.	Physically		
7.	Safe electrical connections.	Physically		
8.	Sufficient room provided for maintenance.	Physically		
9.	Equipment identification name plate should be visible.	Physically		
10.	Units installed on foundation are secure in place as per manufacturer's recommendations.	Physically		
11.	Verify that there is no observable physical damage of following components			
12.	Charging and discharge Hooper.	Physically		
13.	Discharge Shroud	Physically		
14.	Drive Arrangement	Physically		



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S.No.	Statement	Method of Verification	Actual Observation	Checked By Sign/Date
15.	Operating Panel	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
Charging Hopper	Should be available.		Visually		
Discharge Hopper	Should be available.		Visually		
Discharge Shroud	Should be available.		Visually		
Impeller	Should be available.		Visually		
Impeller Shaft	Should be available.		Visually		
Screen	Should be available.		Visually		
Castor wheel	Should be available.		Visually		
	Qty.	04	Visually		
	Specification	2 castors with brake and 2 without brake.	Visually		
Motor	Make	Crompton Greaves	Visually		
	Specification	HP-5, RPM-1440, 415v, FLP, 50 Hz.	Visually		
	Sr. No.	To be recorded	Visually		
VFD	Make	To be recorded	Visually		
	Specification	5HP	Visually		
Timer Belt	Should be available.		Visually		
Limit switch	Should be available		Visually		



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System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
Proxy Sensors for RPM Counter	Should be available.		Visually		
Operating Cum Control Panel	Should be available.		Visually		
Indication Lamp	Should be available.		Visually		
Emergency stop.	Should be available.		Visually		
Start and stop push button.	Should be available.		Visually		
RPM meter with display unit.	Should be available.		Visually		
	Make	Selectron	Visually		
Increase and decrease push buttons.	Should be available.		Visually		
Air Filter	Should be available.		Visually		
	Make	Krishna	Technical Certificate		
	Efficiency	20 μ			
	Capacity	70 CFM			
Power panel	Components	VFD MCB, Relay, On/Off rotary switch Should be available.	Visually		



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Remark: -----

Reviewed by (Sign/Date)



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5.5 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
Charging Hopper	SS316L	Molybdenum kit/ Test Certificate		
Discharge Shroud	SS316L	Molybdenum kit/ Test Certificate		
Impeller	SS316L	Molybdenum kit/ Test Certificate		
Screen	SS316L	Molybdenum kit/ Test Certificate		
Castors	PU	Test Certificate		
Screen	SS 316L	Molybdenum kit/ Test Certificate		
Shaft	SS 316L	Molybdenum kit/ Test Certificate		
Operating Cum Control Panel	SS 304	Molybdenum kit/ Test Certificate		
Filter Assembly	SS316	Molybdenum kit/ Test Certificate		
Gasket	Silicone rubber	Test Certificate		

Remark: -----

Reviewed by (Sign/Date)



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5.6 IDENTIFICATION OF SUPPORTING UTILITIES:

Utility	Method of verification	Observation	Checked by Sign/ Date
Electricity: 3 phase, 415V AC, 50Hz, 5 HP supply with neutral and proper earthing.	Clamp Meter		

Remark: -----

Reviewed by (Sign/Date)



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5.7 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
Earthing	To avoid electrical shocks due to leakage of current.	Physically		
Gasket	To prevent dusting while operation	Physically		
Motor housing	To guard moving part	Physically		
Impeller motor overload	Impeller motor will not run under heavy load.	Physically		
Emergency stop	To stop machine incase of emergency.	Physically		
Shroud and Hopper interlock.	Impeller will not run if the shroud is opened.	Physically		

Remark: -----

Reviewed by (Sign/Date)



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5.8 IDENTIFICATION OF COMPONENT TO BE CALIBRATED:

Name of Components	Range	Make	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 operation of Super Mill.

S.No.	SOP TITLE	IDENTIFIED BY	DATE

Remark: -----

Reviewed by (Sign/Date)



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5.10 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)



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5.11 ABBREVIATIONS:

Following Abbreviations are used in the installation qualification protocol of Super Mill.

MOC: Material of construction

RPM: Rotation per minute

MCB: Miniature circuit breaker

PO : Purchase Order

SS: Stainless Steel

SOP: Standard Operating Procedure

VFD: Variable Frequency Drive



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5.12. LIST OF ANNEXURES:

Annexure No.	Document Title

Remarks (if any):

Done By & Date:

Verified By & Date:



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5.13 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 mentioned in 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 qualification report of Super Mill have been reviewed, found to be acceptable and all variations or discrepancies (If applicable) have been satisfactorily resolved.

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