



PHARMA DEVILS

**INSTALLATION QUALIFICATION
FOR
COLLOIDAL 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 colloid 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		
			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 colloid mill and define the qualification requirements and acceptance criteria for the unit. Successful completion of these qualification requirements will provide assurance that the colloid mill was installed as required in Gelatin preparation room.

The Qualification of Colloid mill performed in view of Gelatin preparation room manufacturing facility.

2.2 PURPOSE:

The purpose of this protocol is to establish documentary evidence to ensure that the Colloid Mill Machine received matches the Design specification and also to ensure that it is properly and safely installed.

2.3 SCOPE:

The installation qualification protocol shall be followed for installation qualification of colloid mill. This protocol defines the methods and documentation that shall be used to evaluate the system installation in accordance with the specifications and intended use. Successful implementation of this protocol shall verify that the systems installed meet the requirements specified.

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.



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

Execution team is responsible for the execution of installation qualification of colloid mill 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 The equipment shall be complying to the specification mention in DQ.
- 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

4.0 REVALIDATION CRITERIA:

The machine has to be revalidated if



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- 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	:	Colloid Mill Machine
Supplier / Manufacturer	:	
Model No.	:	
Serial No.	:	
Particle size reduction	:	5 to 10 micron
Output	:	120 to 12,000 kg/shift.
Area	:	Gelatin preparation room
Hopper capacity	:	30 lit.
Overall Dimension	:	850 mm x 440 mm x 1410 mm ($\pm 10\%$)

Colloid mill is suitable for Homogenizing, Emulsifying, Dispersing, Mixing, & Comminuting of liquids to highly viscous products. It is based on rotor-stator principle.

Three way cock system is provided for draining & recirculation of liquids as standard. Extra discharge spout provided as a standard for viscous products.

Colloid mill machine comprises of following components.

1. Hopper
2. Three way cock system
3. Stator- Rotor
4. Main Motor
5. Push Button
6. Castor Wheel



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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.

5.3 INSTALLATION CHECKLIST:

Installation checklist is 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.		



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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
1.Hopper	Spec.	SS 316L	Test Certificate		
2.Three way cock system	Spec.	SS 316L	Test Certificate		
3.Stator- Rotor	Spec.	SS 316	Test Certificate		
4.Main Motor	Make	New Bharat	Visually From Tag		
	Spec.	Supply- 415 V, 3 Phase AC, 50 Hz, 5 HP, Frame- 100 L FLP Motor Speed- 2800 RPM	Visually From Tag		
	Sr. No.	To be recorded	Visually From Tag		
5. FLP Starter	Relay	5.5-8 AMP	Physically/ Technical Specification		
	Make	FCG	Physically/ Technical Specification		



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System Components	Design Specification		Method Of Verification	Actual Observation	Checked By Sign / Date
6.Push Button	Green Colour Start Button	One	Physically		
	Red Colour Stop Button	One	Physically		
7.Castor wheel	2 Nos. with break & 2 Nos. without break (MOC- PU Wheel)		Physically/ Technical Specification		
	Make	Swift	Physically/ Technical Specification		
	Model	M-AMP-07532	Physically/ Technical Specification		
	Size	Ø 75 x 32 mm	Physically/ Technical Specification		

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
Hopper & Hopper Lid	SS316L	Molybdenum Kit/Test Certificate		
Discharge Spout	SS316L	Molybdenum Kit/Test Certificate		
Rotor Shaft	SS316L	Molybdenum Kit/Test Certificate		
Cock Body	SS316L	Molybdenum Kit/Test Certificate		
Cock Pipe	SS316L	Molybdenum Kit/Test Certificate		
Upper & Lower Stator	SS316L	Molybdenum Kit/Test Certificate		
Housing	SS316L	Molybdenum Kit/Test Certificate		
Rotor	SS316	Molybdenum Kit/Test Certificate		

* Test certificate to be verified and attached to protocol.

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, 50 Hz supply with neutral and proper earthing	Physically challenging with clamp meter		

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	Checked By Sign/ Date
Earthing	Equipment connected with earthing strip	Physically		
Castor wheel with lock.	To avoid the accident during operation due to the movement of equipment.	Physically		
Guards	Motor is housed in a C.I. housing	Physically		

Remark: -----

Reviewed by (Sign/Date)



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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 colloid mill.

S.No.	SOP Title	Verified By Sign/ Date

Remark: -----

Reviewed 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 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 qualification report of Colloid Mill have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

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