PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR OPERATIONAL QUALIFICATION OF COLLOIDAL MILL	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 authorities.

This Operation Qualification protocol of Colloid mill has been reviewed and approved by the following Persons:

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 Colloid Mill Machine 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.

The Qualification of Colloid mill performed in view of Gelatin preparation room of 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 Scope of this protocol is limited to the operational Qualification of Colloid Mill Machine.

Once the operational qualification of Colloid Mill Machine has been completed successfully, the equipment shall be preceded for the 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 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 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.

2.5 EXECUTION TEAM:

The satisfactory operation of the Colloid Mill Machine shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the Colloid Mill Machine is operational and is satisfactorily working.

Execution team is responsible for the execution of installation of Colloid Mill Machine. Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 ACCETANCE 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 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 ± 5% range.

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.

5.0 OPERATIONAL 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 (± 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

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 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 colloid mill.

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

Remarks:

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

5.4 Test instrument calibration:

Review the calibration status for the test instrument to be utilized in operational qualification testing and record the calibration due dates in the table below. All equipment/instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilized.

S.No.	Test Instrument	ID	Calibration done Date	Calibration Due Date	Calibration Certificate No

Remarks:

Checked By/Date: **Verified By/Date:**

5.5 VERIFICATION OF FUNCTIONAL CHECKS:

5.5.1 Verification of functionality major component

NAME OF SYSTEM COMPONENT	SPECIFIED FUNCTION	METHOD OF VERIFICATION	OBSERVATION	VERIFIED BY SIGN /DATE
1.Hopper	For holding the solution	Physically		
2.Three way cock system	For recirculation of the liquid	Physically		
3.Stator Rotor	For size reduction to colloid size	Physically		
4.Main Motor	To start the operation	Physically		
5.Push Button	To start & stop the machine	Physically		
6. Castor wheel with lock	Locking arrangement for wheel is provided to avoid the movement of machine during operation	Physically		

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

Reviewed by (Sign/Date)

5.5.2 Verification of operation key functionality:

Name of System Component	Specified Function	Method of Verification	Observation	Verified By Sign/Date
Main power ON with green push button	Machine should start	By challenging		
Main power OFF with red push button	Machine should stop	By challenging		

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

Reviewed by (Sign/Date)

5.6 VERIFICATION OF SUPPORTING UTILITIES:

Utility	Method of Verification	Observation	Verified By Sign/Date
Electricity: 3 phase, 415V AC, 50Hz supply with neutral and proper earthing	By challenging with clamp meter		

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

Reviewed by (Sign/Date)

5.7 VERIFICATION OF SAFETY FEATURES:

SAFETY FEATURES DESCRIPTION	FUNCTION	VERIFIED BY (SIGN)	DATE
1. Earthing	To avoid electrical shocks due to leakage current		
2. Leakage of liquid	Oil seal and "O" rings are provided to avoid the leakage of the liquid		
3. Castor wheel with lock	To avoid the accident during operation due to the movement of equipment		

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

Reviewed by (Sign/Date)

5.8 VERIFICATION OF STANDARD OPERATING PROCEDURE (SOP)

The following Standard Operating Procedures were verified as important for effective performance of colloid mill machine operation.

S.No.	SOP TITLE	SOP NUMBER	VERIFIED BY	DATE

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

Reviewed by (Sign/Date)

5.9 TRAINING RECORD OF PERSONNEL (S) :

S.No.	Name of Personnel	Designation	Sign. & Date	Trained By	Remark
1.					
2.					
3.					
4.					
5.					

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

Reviewed by (Sign/Date)

5.10 LIST OF ANNEXURES:

Annexure No.	Document Title

Remarks (if any)**:**

_____

_____

_____

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

5.11 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)

6.0 OPERATIONAL QUALIFICATION FINAL 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. If applicable signature in the block below indicates that all items in this Operational 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		