PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR COLLOIDAL MILL	PROTOCOL No.:

1.0 REPORT 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 performance qualification protocol of Colloidal 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		
			QUALITY CONTROL		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		

2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of developing and executing this protocol is to

- Document the verification of all aspects of the equipment that can affect product quality.
- To establish, check and document the performance of equipment in the established/predetermined operating ranges.

2.2 PURPOSE:

The purpose of this protocol is to verify that the equipment produces the desired output. Performance qualification of the equipment is planned after the successful completion of the installation and operational qualification.

The equipment working capacity is recommended by manufacturer challenged by charging the tablets with the maximum and minimum capacity of the pan.

2.3 SCOPE:

The protocol shall define the test procedures, documentation, references and acceptance criteria to establish that the performance of the equipment shall meet the predetermined acceptance criteria.

The Scope of this protocol is limited to the performance qualification of Colloidal Mill of manufacturing facility at …….

Once the performance qualification of Colloidal Mill has been completed successfully, the equipment shall be released for the production purposes.

2.4 RESPONSIBILITY:

In accordance with protocol, following functions shall be responsible for the qualification of system.

Execution Team (Comprising members from Production, Quality control , Engineering and Quality Assurance) and their responsibilities are following:

- Prepares the performance 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 analysis of sample shall be carried out by quality control department.
- Engineering department shall support for execution.
- The production operator/supervisor shall carry out the cleaning and operation of machine.

Head – Quality control/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 Colloidal Mill shall be verified by executing the performance qualification studies described in this protocol. The successfully executed protocol documents that the Colloidal Mill is operational and is satisfactorily working.

Execution team is responsible for the execution of performance qualification of the Colloidal Mill. Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 PREREQUISITE

3.1 Approved Standard operating procedure of the equipment shall be available.

3.2 The maximum and minimum capacity of the equipment shall be verified by taking the batch/lot to suit the requirement.

3.3 The installation and operational qualification of the equipment shall be successfully completed before the execution of the performance qualification.

3.4 All the deficiencies and discrepancies related to the equipment which affect the product quality and corrective action taken shall be recorded in the appropriate section of the protocol.

3.5 After completion of PQ activities, equipment shall be cleaned as per respective cleaning SOP's and released for manufacturing.

4.0 REVALIDATION CRITERIA:

The machine shall be re-validated if

- There are any major changes, which affect the performance of the equipment.
- After major breakdown maintenance is carried out.
- As per re-validation date and schedule

5.0 PERFORMANCE QUALIFICATION PROCEDURE:

5.1 BRIEF DESCRIPTION OF EQUIPMENT

Colloidal mill machine comprises of following components:

1. Hopper
2. Three way cock system
3. Stator Rotor
4. Body cover
5. Electronic motor

The purpose of colloidal mill is Homogenizing, Emulsifying, Dispersing, Mixing and communicating of liquids to highly viscous product:

1. Motor Housing Assembly
2. Extension Housing Assembly
3. Main housing assembly
4. Cock Body Assembly

The speed of the rotor is high. To increase the gap between stator and rotor de-lock the handles by unscrewing the turn adjusting ring by rotating the handles anticlockwise and to increase the milling rotate the handles clockwise and also lock the handles.

Due to slightly deviating tapering of the milling surfaces of stator and rotor, the gap becomes narrower towards the discharge section. The special design type facilitates adjustment of the grinding gap by an exterior screw ever during operation.

By three way cock assembly we can re-circulate liquid type product till you get your required result. The system has utilities like electrical connection and chilled water connection connected to it.

5.2 Risk Analysis:

- The Colloidal Mill is used for Homogenizing, Emulsifying, Dispersing, Mixing purpose of colour slurry.

S.No.	Risk identified	Control measures
1.	Temperature of the product	Product is thermolabile and manufactured at room temperature.
2.	Temperature of the jacket	Product is thermolabile and manufactured at room temperature so there is need to control of jacket temperature

EVALUATION & CONCLUSION

All the risks associated with Colloidal Mill have been evaluated and control/preventive measures have been taken.

5.3 Methodology:

Methodology of the Colloidal Milling is as follows:

- Colloidal Mill is used to Homogenizing, Emulsifying, Dispersing, Mixing purpose of colour slurry.
- The PQ of the Colloidal Mill shall be done on PQ Batch manufactured under BMR No. _____ .
- Maximum holding of slurry in the hopper shall be 20 Liters.

5.4 PRODUCT PROFILE:

Product details of the batches shall be verified from the BPR of the product and record in the following section:

Product Detail:

Product details shall be verified from the BMR of the product and record in the following table:

S.No.	Name of Product	Batch No.	Batch Size

Inference:

_____

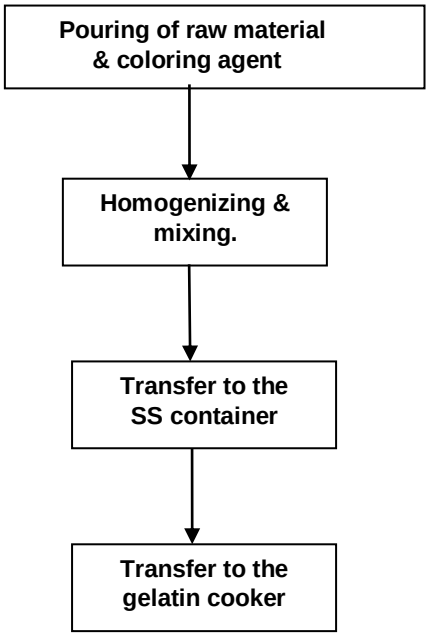
_____

_____

Reviewed By
Sign & Date

5.5 PROCESS FLOW DIAGRAM WITH QUALIFICATION PARAMETERS OF COLLOIDAL MILL:

Process flow diagram of Colloidal Mill is mentioned below:



5.6 SAMPLING MATRIX:

No sampling is required in the Performance Qualification of the Colloidal Mill.

5.7 VERIFICATION OF PERFORMANCE QUALIFICATION:

Test Parameter	Specified Function	Observations	Verified By (Sign. & Date)
Physical Appearance of Colour slurry	Colour slurry shall be free from lumps, homogenized and free from gritty particles		
Mill Capacity	Mill operates trouble free at capacity agreed with Supplier		

Inference:

_____

_____

_____

Reviewed By
Sign & Date

5.8 ACCEPTANCE CRITERIA:

The test will be considered failed if the actual test results do not correspond to the expected results as following:

- Colour slurry shall be free from lumps, homogenized and free from gritty particles.
- Mill operates trouble free at capacity agreed with Supplier.

6.0 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)

7.0 PERFORMANCE QUALIFICATION FINAL REPORT:

7.1 SUMMARY:

7.2 CONCLUSION:

Prepared By
Sign/Date

Checked By
Sign/Date

7.3 FINAL REPORT APPROVAL

The final report shall be signed after verifying that all the tests required in the qualification report of Colloidal Mill are completed, reconciled and attached to the Qualification report or included in the qualification summary report and also verified that all amendments and discrepancies are documented, approved and attached to respective report. (If applicable) Signature in the block below indicates that all items in the qualification report of Colloidal Mill have been reviewed and found to be acceptable and that all variations or discrepancies (if any) have been satisfactorily resolved.

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