PERFORMANCE QUALIFICATION PROTOCOL
FOR
COLLOID MILL

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EQUIPMENT ID. No.	
LOCATION	**Solution Preparation**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

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1.0 PROTOCOL APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

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2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all test parameters meet the pre-defined acceptance criteria

3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for Colloid Mill.
- This Protocol will define the methods and documentation used to qualify the Colloid Mill for PQ.

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4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review and Authorization of the Performance Qualification Protocol. • Co-ordination with Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification Protocol.
Production	• Review and Approval of Protocol. • To co-ordinate and support Performance Qualification Activity.
Engineering	• Reviewing of qualification protocol for correctness, completeness and technical excellence. • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule.

4.1 Qualification Team:

- All the persons involved in Qualification activity detail in below table.

Name	Department	Designation	Sign & Date

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5.0 EQUIPMENT DETAILS:

Equipment Name	Colloid Mill
Equipment	
Manufacturer's Name	Chamunda Pharma Machinery Pvt. Ltd
Machine S. No.	
Supplier's Name	Chamunda Pharma Machinery Pvt. Ltd
Location of Installation	Solution Preparation

6.0 EQUIPMENT DESCRIPTION:

This equipment is a self contained a protable unit for the process of size reduction.It uses the principle of Impact in Air. The product is dropped axially from the feed hopper. In a communication chamber where it comes in contact with blades (Either the Knife edge or the impact edge) rotating at high speed.

Operating speed are variable & can be varied in steps of 750/1500/2100/3000 by a simple & design of placing the "V" belt in the desired groove of a multi-groove pulley.

Operating parts can be dismantled & assembled quickly, thereby saving down time during cleaning.

A safety limit switch can be incorporated in the top cover so as to switch off the equipment as soon as the cover is opened (optional)

Screen range from

Perforated 0.5 mm to 25 mm in S.S. 316 /304 quality.

Wire mesh with backup frame-4 mesh to 80 mesh in S.S. 316/304 quality.

Special Hollander weave screen of 110/24 mesh in S.S. 316/304 quality.

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7.0 REASON FOR QUALIFICATION:

- New Equipment installed in Solution Preparation.
- After completion of the Operation Qualification of the Equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

8.0 SITE OF STUDY:

Solution Preparation.

9.0 FREQUENCY OF QUALIFICATION:

- Once in every Five year ±1 month.
- After any major breakdown or after major modification.
- After Change of Location.

10.0 PRE – QUALIFICATION REQUIREMENTS:

10.1 Verification of Documents:

The below mentioned activities should be completed prior to commencing the performance qualification activity:

- Executed and approved Design Qualification document.
- Executed and approved Installation Qualification document.
- Executed and approved Operational Qualification document.
- SOP for Operating & Cleaning of Colloidal Mill.
- SOP for Preventive Maintenance Colloidal Mill.

Procedure:

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved.
- Supporting documents would form a part of the PQ report.

Acceptance Criteria:

All the documents should be available, complete and approved by respective authorities.

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11.0 TESTS AND CHECKS:

11.1 REPORT OF PERFORMANCE EVALUATION USING PRODUCT:

Purpose:

The objective of this test is to ascertain an approved particle size of the dispensed/ milled powder for the Granulation process.

Method

Install/ ensure mesh of size as identified in BMR. Mesh opening of the Sieve to be as identified as per BSS Mesh number.

The dispensed/milled material is charged through scooping into the hopper of the colloidal mill. The quantity & type of material charged and the size of the sieve selected shall be as per BMR. The sieving is carried out as per approved parameters, in accordance with Standard Operating Procedures & as per BMR.

Samples of milled material are taken at the high, middle & slow speed of the milling process from the discharge chute of the colloidal mill.

The samples are analyzed for appearance and particle size by manual sieving through an analytical sieve of approved mesh size.

Acceptance Criteria:

Granules of the respective size are passes through the respective mesh.

12.0 CHECKLIST OF ALL TESTS AND CHECKS:

A checklist shall be provided to ensure that all tests or checks required for this protocol have been executed. After execution observations shall be recorded in Performance Qualification Report.

The list includes:

- Verification of DQ, IQ & OQ & other documents.
- Verification of performance using Drug product.

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13.0 REFERENCES:

The Principle Reference is the following:

- Validation Master Plan
- Schedule-M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition/March 2001.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.

14.0 DOCUMENTS TO BE ATTACHED:

- Any other relevant document.

15.0 NON COMPLIANCE:

- In case of any non compliance observed during PQ, inform to Head QA for necessary action.
- The Head QA shall study the impact of non compliance. If non compliance is acceptable and it does not have an impact on operation as well as on performance of the machine, prepare final conclusion.

16.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

17.0 CHANGE CONTROL, IF ANY:

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

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18.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practices
COL	:	Colloid mill
DQ	:	Design Qualification
EU	:	European Union
FDA	:	Food and Drug Administration
ID.	:	Identification
IQ	:	Installation Qualification
Kg	:	kilogram
mg	:	Milligram
mm	:	Millimeter
OQ	:	Operational Qualification
PPQ	:	Performance Qualification Protocol
QA	:	Quality Assurance
SOP	:	Standard Operating Procedure