PERFORMENCE QUALIFICATION

PROTOCOL

FOR

COMMINUTING MILL

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

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR COMMINUTING MILL	PROTOCOL No.:

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PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR COMMINUTING MILL	PROTOCOL No.:

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)			

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 Comminuting Mill **(Make ……...)** installed in the Granulation.
- This Protocol will define the methods and documentation used to qualify the Comminuting Mill for PQ.

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, Authorization, Review and Compilation of the Performance Qualification. • Co-ordination with Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• 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.

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5.0 EQUIPMENT DETAILS:

Equipment Name	Comminuting Mill
Equipment ID.	
Model	
Sr. No.	
Manufacturer's Name	Cadmach Machinery Pvt. Ltd.
Supplier's Name	Cadmach Machinery Pvt. Ltd.
Location of Installation	Granulation

6.0 SYSTEM DESCRIPTION:

Comminuting Mill is use for Particle Reduction / Dry Granulation and Wet Granulation. The Efficiency of mill is determined by the large Screen area. Which is presented to the material in the Comminuting chamber, whilst its Flexibility is affected through. the verity of relationship possible by different combinations of speed, screen aperture size and type of blades. By a choice of these variables, a precisely determinable final product is attainable. The mill is Built throughout of SS and Consists of a chamber, the lower part of which holds an interchangeable screen. A shaft carrying a rotor passes throughout the chamber, and to this rotor a carrying a rotor passes throughout the chamber .and to this rotor numbers of blades are attached. The material is fed into the chamber by means of a feed hopper. The chamber itself is held onto a base frame by another four bolts material is fed from the bins, down a feed throat to the rotating blades, and then through a screen. The Speed of the rotor can be varied by using step pulley with three different speeds. The Chamber of the mill is provided with three different speeds. The chamber is mounted on the machine frame. Chamber of the mill is provided with water jacketed system.

7.0 REASON FOR QUALIFICATION:

- New equipment in Granulation.

8.0 SITE OF STUDY:

Granulation.

9.0 FREQUENCY OF QUALIFICATION:

- Once in every five years + 1 Month time period.
- After any major breakdown or after major modification.

10.0 PRE – QUALIFICATION REQUIREMENTS:

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

- Preparation of SOP for Operation & Cleaning of comminuting mill.
- Preparation of SOP for Preventive Maintenance Comminuting mill.

11.0 TESTS AND CHECKS:

11.1 Evaluation of Performance Using Drug Products:

Objective:

- To verify the performance of equipment in the range of operational parameters established in Operational Qualification Activity.
- To establish documented evidence that the Comminuting Millis performing consistently and the result of all test parameters meet the pre - defined acceptance criteria of milled products.

11.1.1 Checks:

- Milling Efficiency.

11.1.2 Method:

- Install screen of specified (in BMR) mesh size.
- The dispensed/milled material is charged through scoop into the hopper of the Comminuting 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.
- Perform milling of weighed quantity the Raw Material (RM-1) through screen of specified mesh size as mentioned in the BMR.
- Milling should be carried out at reverse/forward knife condition as per granules stage.
- Record the direction of blades.
- Perform visual checks for integrity of sieve.
- Weight the total quantity of material added for milling at the optimum speed of the milling process from the discharge chute of the Comminuting Mill.
- Calculate the “% passed through screen & % retained on screen.
- Record the observations in the report.
- Perform the same procedure using Different Raw materials (RM-1, RM-2 & RM-3).

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

12.0 CHECKLIST OF ALL TESTS & 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 performance using Drug product.

13.0 REFERENCES:

The Principle References are as following:

- Validation Master Plan
- Schedule-M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2 – Good Manufacturing Practices and Inspection.

14.0 DOCUMENTS TO BE ATTACHED:

- Any other relevant document.

15.0 NON COMPLIANCE:

- All the Non-compliances of procedure, specifications, and sampling, analysis and documentation activities shall be monitored & recorded.

16.0 DEVIATION FROM PRE-DEFINED 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 any 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.

18.0 ABBREVIATIONS:

WHO	:	World Health Organization
cGMP	:	Current Good Manufacturing Practices
QA	:	Quality Assurance
PQ	:	Performance Qualification
SOP	:	Standard Operating Procedure
MOC	:	Material of Construction
NLT	:	Not Less Than