PERFORMANCE QUALIFICATION

PROTOCOL

FOR

MULTI MILL

EQUIPMENT ID. No.	
LOCATION	
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

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PROTOCOL CONTENTS

PERFORMANCE QUALIFICATION PROTOCOL FOR MULTI MILL

1.0 PROTOCOL -APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

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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 Multi Mill **(Make- Elicon Pharma)** installed in the Granulation.
- The Multi Mill is a standalone unit with plug in type electrical connections for operation and is on castor wheel. Hence, may be moved as per requirement to other area of operation which shall not change the performance of equipment.
- This Protocol will define the methods and documentation used to qualify the Multi 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 cum Report.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Initiation, Review, Approval and Compilation of the Performance Qualification. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review of Performance Qualification Protocol. • To co-ordinate and support Performance Qualification Activity.
Engineering	• Review of Performance 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	Multi Mill
Equipment ID.	
Manufacturer's Name	Elicon Pharma
S.No.	EP/P&CHPL/MM-3HP/8/AUG/2014
Supplier's Name	Elicon Pharma
Location of Installation	

6.0 SYSTEM DESCRIPTION:

Milling is an important step in pharmaceutical manufacturing process. This equipment is a self contained & portable unit for the process of size reduction. It uses the principle of impact of air. The product is dropped axially from the hopper in a communication chamber where it comes in contact with blades (either the knife edge or the impact edge) rotating at high speed.

Multi Mill is basically an acceleration type miller where the powders milled are subjected to acceleration force created by centrifugal force and gravity. Multi Mill is used for rapid milling of dry and semi – dry products. The central portion of the Multi Mill is provided with unique designed blades. Top portion of the machine is provided with feeder for material feeding. The milling is accomplished quickly and with most products within few minutes.

7.0 REASON FOR QUALIFICATION:

- New equipment in Granulation.
- After completion of the Operational 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:

Granulation.

9.0 FREQUENCY OF QUALIFICATION:

- Once in every two year.
- After any major breakdown or after major modification.

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10.0 PRE – QUALIFICATION REQUIREMENTS:

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

- Design Qualification.
- Installation Qualification.
- Operational Qualification.
- SOP for Operation & Cleaning of Multi mill.
- SOP for Preventive Maintenance Multi mill.

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11.0 TESTS AND CHECKS:

11.1 Verification of Documents:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the Performance qualification report.

- Executed and approved Design Qualification document.
- Executed and approved Installation Qualification document.
- Executed and approved Operational Qualification document.
- SOP for Operation & Cleaning of Multi mill.
- SOP for Preventive Maintenance Multi 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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11.2 Evaluation of Performance Using Placebo Formulation:

Objective

- To verify the performance of equipment in the range of operational parameters established in Operational Qualification Activity.
- To establish the Performance based range of operating parameters for performance qualification activity using placebo.

11.2.1 Checks:

- Particle Size of the dispensed/milled powder for the Granulation process.

11.2.2 Method:

- Install sieve of specified mesh size.
- Load weighed quantity the materials to through scooping into the hopper of the multi mill
- The quantity & type of material charged and the size of the sieve selected shall be as per BMR.
- Perform milling.
- Record the milled granule % by percentage of retained granule.
- Perform visual checks for integrity of screen.
- Record the observations in the report.
- Perform the procedure using screen of 3 different mesh sizes.

11.2.3 Acceptance Criteria:

- Granules of the respective size are passes through the respective mesh.
- % Retain Granule : NMT 5%
- Black Particle : Should be Absent
- Integrity of Screen : Integrated

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11.3 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 Multi Mill is performing consistently and the result of all test parameters meet the pre – defined acceptance criteria of milled products.

11.3.1 Checks:

- Milling Efficiency

11.3.2 Method:

- Install screen of specified (in BMR) mesh size.
- Perform milling of weighed quantity the Raw Material (RM-1) through screen of specified mesh size as mentioned in the BMR.
- Record the milled granule % by percentage of retained granule
- Perform visual checks for integrity of sieve.
- Weight the total quantity of material added for milling at the high, medium & slow speed of the milling process from the discharge chute of the Multi Mill.
- Rotate the blade in forward direction.
- Record the quantity of material retained on screen.
- 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.

11.3.3 Acceptance Criteria:

- Granules of the respective size are passes through the respective mesh.
- % Retain Granule : NMT 5%
- Black Particle : Should be Absent
- Integrity of Screen : Integrated

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 DQ, IQ & OQ & other documents.
- Verification of performance using placebo formulation.
- 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, 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 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.

18.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practice
mm	:	Millimeter
P & ID	:	Piping and Instrumentation Diagram
PO	:	Purchase Order
QA	:	Quality Assurance
SS	:	Stainless Steel
STD	:	Standard
PPQ	:	Performance Qualification Protocol
MML	:	Mutimill
WHO	:	World Health Organization