PERFORMANCE QUALIFICATION

REPORT

FOR

MULTI MILL

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

PERFORMANCE QUALIFICATION REPORT FOR MULTI MILL

REPORT CONTENTS

PERFORMANCE QUALIFICATION REPORT FOR MULTI MILL

1.0 REPORT PRE-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)			

PERFORMANCE QUALIFICATION REPORT FOR MULTI MILL

2.0 OBJECTIE:

- 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 Report covers all aspects of Performance Qualification for the **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.
- The report provides all the relevant information of Performance Qualification Activity for Multi Mill and all the observation of in-process checks and analytical results of analyzed samples.

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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 Report.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Initiation, Review, Approval and Compilation of the Performance Qualification Report. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification . • Post Approval of Performance Qualification Report after Execution.
Production	• Review of Performance Qualification Report. • To co-ordinate and support Performance Qualification Activity. • Post Approval of Performance Qualification Report after Execution.
Engineering	• Review of Performance Qualification report for correctness, completeness and technical excellence. • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule. • Post Approval of Performance Qualification Report after Execution.

PERFORMANCE QUALIFICATION REPORT FOR MULTI MILL

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	Granulation

6.0 PRE – QUALIFICATION REQUIREMENTS:

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.

PERFORMANCE QUALIFICATION REPORT FOR MULTI MILL

7.0 TESTS AND CHECKS:

7.1 Verification of Documents:

Record the observations for documents in the below mentioned table.

S.No.	DOCUMENT NAME	DOCUMENT /SOP No.	COMPLETED (YES/NO)	CHECKED BY (ENGINEERING) SIGN/DATE	VERIFIED BY (QUALITY ASSURANCE) SIGN/DATE
1.	Executed and approved Design Qualification document				
2.	Executed and approved Installation Qualification document				
3.	Executed and approved Operational Qualification document				
4.	PQ Protocol approved				
5.	SOP for Operation & Cleaning of Multi Mill				
6.	SOP for Preventive Maintenance				

Inference:

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Reviewed By
(Manager QA)
Sign & Date: ……

PERFORMANCE QUALIFICATION REPORT FOR MULTI MILL

7.2 TEST PRODUCT BATCH INFORMATION:

S.No.	PRODUCT NAME	BATCH	BATCH	MFG.	EXPIRY
Placebo Formulation					
Drug Products					

Compiled By
(QA)
Sign/Date: ……..

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FOR MULTI MILL

7.3 REPORT OF PERFORMANCE EVALUATION USING PLACEBO FORMULATION:

Product Name: **Batch No:**

SCREEN SPECIFIED AS PER BMR	SIEVE SPECIFIED AS PER BMR	% GRANULES PASSED	% GRANULES RETAINED	BLACK PARTICLES	INTEGRITY OF SCREEN & SIEVE	
					BEFORE	AFTER

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FOR MULTI MILL

7.4 REPORT OF PERFORMANCE EVALUATION USING DRUG PRODUCTS:

In-Process Observations:

Product name	Batch No.	Screen specified As per BMR	Sieve specified As per BMR	% Granules passed	% Granules retained	Black Particles	Integrity of screen & sieve	
							Before	After

Direction of rotation of blades:

Acceptance Criteria	
% Retain Granules	NMT 5%
Black Particles	Should be absent
Integrity of Screen &	Should be Integrated

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PERFORMANCE QUALIFICATION REPORT FOR MULTI MILL

8.0 CHECKLIST OF ALL TESTS & CHECKS: This checklist is provided to ensure that all tests or checks required for this protocol have been executed.

TESTS OR CHECKS	EXECUTED (YES/NO)	REMARKS
Verification of DQ, IQ & OQ & other documents.		
Verification of performance using Placebo Formulation.		
Verification of Performance using Drug Products.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

9.0 DOCUMENTS TO BE ATTACHED:

- Any other relevant document

10.0 NON COMPLIANCE:

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11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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12.0 CHANGE CONTROL, IF ANY:

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13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY)

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14.0 CONCLUSION

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15.0 RECOMMENDATION

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16.0 ABBREVIATIONS:

DQ	:	Design Qualification
ID.	:	Identification
IQ	:	Installation Qualification
Kg	:	Kilogram
mm	:	Millimeter
NLT	:	Not Less Than
OQ	:	Operational Qualification
PQ	:	Performance Qualification
QA	:	Quality Assurance
SOP	:	Standard Operating Procedure

17.0 REPORT POST- 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)			