



PHARMA DEVILS

**PERFORMANCE QUALIFICATION REPORT
FOR
COMMINUTING MILL**

PROTOCOL No.:

**PERFORMANCE QUALIFICATION
REPORT
FOR
COMMINUTING MILL**

EQUIPMENT ID No.	
LOCATION	Granulation
DATE OF QUALIFICATION	
SUPERSEDES REPORT No.	NIL



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1.0 REPORT PRE – 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 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:

- This Report covers all the aspects of Performance Qualification for the **Comminuting Mill (Make:)** installed in **Granulation**.
- This Report will define the methods and documentation used to qualify the Comminuting 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 Report.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Preparation, Authorization, review and Compilation of the Performance Qualification.• Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity.• Monitoring of Performance Qualification.
Production	<ul style="list-style-type: none">• Approval of Report.• To co-ordinate and support Performance Qualification Activity.
Engineering	<ul style="list-style-type: none">• Reviewing of qualification Report 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 PRE – QUALIFICATION REQUIREMENTS:

6.1 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.	PQ Protocol approved				
2.	SOP for Operation & Cleaning of Comminuting Mill				
3.	SOP for Preventive Maintenance Comminuting Mill				

Inference:

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



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7.0 TESTS AND CHECKS:

7.1 TEST PRODUCT BATCH INFORMATION:

S.No.	Product Name	Batch No.	Batch Size	Mfg. Date	Expiry
Drug Products					

Compiled By

(QA)

Sign/Date:

Inference:

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Reviewed By

(Manager QA)

Sign/Date:



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7.2 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

Acceptance Criteria

% Retain Granules	NMT 5%
Black Particles	Should be absent
Integrity of Screen & Sieve	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:



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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 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:

CDL	:	Comminuting Mill
IQ	:	Installation Qualification
Kg	:	Kilogram
Ltd	:	Limited
MOC	:	Material of Construction
NLT	:	Not Less Than
PQ	:	Performance Qualification
Pvt	:	Private
QA	:	Quality Assurance
SOP	:	Standard Operating Procedure



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17.0 REPORT POST – 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)			