



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MILL

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
MULTI MILL**

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



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MILL

PROTOCOL CONTENTS

S.No.	TITLE	PAGE No.
1.0	Protocol Pre-Approval	3
2.0	Objective	4
3.0	Scope	4
4.0	Responsibility	5
5.0	Equipment Details	6
6.0	System Description	6
7.0	Pre-Qualification Requirements	7
8.0	Critical Variables to be Met	8-13
9.0	References	14
10.0	Documents to be Attached	14
11.0	Deviation from Pre-Defined Specification, If Any	14
12.0	Change Control, If Any	14
13.0	Review (Inclusive of follow up action, If Any)	15
14.0	Conclusion	15
15.0	Recommendation	15
16.0	Abbreviations	16
17.0	Protocol Post Approval	17



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MILL

1.0 PROTOCOL 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)			



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2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Multi Mill for
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of **Multi Mill (Make – Elicon Pharma)** installed in the **Granulation- 08, First Floor ‘G’ Block** at
- Equipment Transfer from
- 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 document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Multi Mill.



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MILL

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	<ul style="list-style-type: none">• Initiation, Review, Approval and Compilation of the Installation Qualification Protocol cum Report.• Co-ordination with Production and Engineering to carryout Installation Qualification.• Monitoring of Installation Qualification Activity.• Post Approval of Installation Qualification Protocol cum Report after Execution.
Production	<ul style="list-style-type: none">• Review & Pre Approval of Installation Qualification Protocol cum Report.• To Co-ordinate and support for Execution of Qualification study as per Protocol.• Post Approval of Installation Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review & Pre Approval of Installation Qualification Protocol cum Report.• Co-ordination, Execution and technical support in Multi Mill Installation Qualification Activity.• Calibration of Process Instruments.• Responsible for Trouble Shooting (if occurs during execution).• Post Approval of Installation Qualification Protocol cum Report after Execution.



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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
Model	GMP Model.
Supplier's Name	Elicon Pharma.
Location of Installation	

6.0 SYSTEM DESCRIPTION:

This equipment is a self-contained a portable 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 600/1500/2100/2800 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 2.5 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 PRE-QUALIFICATION REQUIREMENTS:

7.1.1 Verification of Documents:

- Executed and approved design qualification document
- GA Drawing
- Technical specification of equipment
- Certificate of material of construction of components.

7.1.2 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. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum report.

7.1.3 Acceptance Criteria:

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



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8.0 CRITICAL VARIABLES TO BE MET:

8.1 Installation Qualification Checklist:

S.No.	INSTALLATION CHECK	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/ DATE
1.	Check for the Dimensional Accuracy		
2.	Check for the receipt of the consignment in good condition		
3.	Check for any scratches on the machine body		
4.	Identify the hoppers with their lids		
5.	Identify the Feed Frame in the working zone		
6.	Identify the Feeding tube		
7.	Check for the electrical panel. All Electrical connections should be as per the Circuit Diagram.		
8.	Check driving component in base cabinet.		

Checked By
(Production)
Sign/Date:

Verified By
(Quality Assurance)
Sign/Date:

Inference:

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



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MILL

8.2 Component Location List:

S.No.	COMPONENT	LOCATION	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/ DATE
1.	Hopper (All types)	On the top of the machine		
2.	Feed Hopper (All types)	Working zone		
3.	Column	Below discharge hopper		
4.	Bearing Housing	Between Bearing 30206 (above) & 30207 (Below)		
5.	Blades	Attached to beater		
6.	Screen	Held by screen holding plate attached to stud		
7.	Screen Holding Plate	Held with stud		
8.	Motor	Positioned above the hopper at the top the machine		
9.	Castor Wheel	At the base		
10.	Gasket	Surrounding hopper(charging & discharging)		

Checked By
(Production)
Sign/Date:

Verified By
(Quality Assurance)
Sign/Date:

Inference:

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



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MILL

8.3 Installation requirement checks:

INSTALLATION CHECK	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/ DATE
Check for machine supported on castor wheel.	Machine supported on 4 Nos. castor wheel to keep machine on level ground		
Check direction of motor	<ul style="list-style-type: none">• Forward should give Clock wise rotation.• Reverse to give Anti-clockwise rotation.		
Check for grease cup on bearing housing	Bearing housing should be fully greased for lubrication. (Recommended grease is MOSIL BRB500).		
Assembled Rotor & the blade.	<ul style="list-style-type: none">• The scraper blades have to be in the lowest.• Blade should be fixed with their knife edge in forward direction.		

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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8.4 MOC Verification List:

S.No.	PARTS NAME	MOC	OBSERVATION
1.	Motor	STD	
2.	Column	AISI 304	
3.	Base	MS with AISI 304 CLADED	
4.	Bearing housing	CI	
5.	S.S Blades	SS316	
6.	Perforated Screen (2mm)	AISI 316	
7.	Screen Holding Plate	AISI 316	
8.	Holding Plate Supporting Bolt & Wing	AISI 316	
9.	Feeding Hopper	SS316	
10.	Intermediate Hopper	SS316	
11.	Discharge Hopper	SS316	
12.	Castor Wheel	Nylon	
13.	Gasket	White Food Grade Silicon	
14.	Teflon Rope	Teflon	
15.	Control Panel	AISI 304	
16.	Push Button	STD	
17.	'V' - Belt	STD. Rubber	

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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8.5 Utility Verification List:

S.No.	UTILITY PARAMETER	SPECIFIED	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN /DATE
1.	Make	“REMI”	“REMI”		
2.	Voltage:	415 ± 5%	415 ± 5%		
3.	HP	3HP	3HP		
4.	RPM	1410	1410		
5.	AMP	4.7	4.7		

Checked By
(Production)
Sign/Date:

Verified By
(Quality Assurance)
Sign/Date:

Inference:

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Reviewed By
(Manager QA)
Sign/Date:



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MILL

8.6 Safety:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATIONS
MCB	MCB is provided so that when there is an overload in current or any short circuit then the MCB trips.	
Mechanical Guard	Mechanical guard for all rotating parts.	
Joints	Welding of joints without any welding burrs.	
Metal Parts	All the metal parts should be properly grounded without any sharp Edges.	
Leveling and Balancing	Equipment should be properly balanced & leveled.	
Electrical Wiring And Earthing	Electrical wiring should be as per approved drawings. Double external Earthing to control machine (panel and motors) and operator should be provided.	
Noise Level	Below 80 db.	
Emergency Switch	Provided easy access position.	

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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9.0 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.”
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2 – Good Manufacturing Practices and Inspection.

10.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC.
- Operation and Maintenance Manual.

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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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MILL

16.0 ABBREVIATIONS:

AISI	:	American Iron and Steel Institute
C.I.	:	Cast Iron
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
HP	:	Hours Power
IQ	:	Installation Qualification
Ltd	:	limited
MCB	:	Miniature Circuit Breaker
mm	:	Millimetre
MML	:	Multi Mill
MOC	:	Material of construction
No.	:	Number
OD	:	Oral Solid Dosage
Pvt	:	Private
QA	:	Quality Assurance
RPM	:	Revolutions per Minute
SS	:	Stainless Steel
V	:	Volts
VFD	:	Variable Frequency Drive



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17.0 PROTOCOL 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)			