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

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MILL

1.0 PROTOCOL PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)	QA Executive	Pharmadevils	01/01/25

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)	Head Production	Pharmadevils	01/01/25
HEAD (ENGINEERING)	Head Engineering	Pharmadevils	01/01/25

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)	Head Quality Assurance	Pharmadevils	01/01/25

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MILL

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** 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.

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 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	• 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	• 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.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MILL

5.0 EQUIPMENT DETAILS

Equipment Name	Multi Mill
Equipment ID.	----
Manufacturer's Name	Elicon Pharma
S.No.	----
Model	GMP Model
Supplier's Name	Elicon Pharma
Location of Installation	Granulation

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.

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.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MILL

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	Verified dimensions by using calibrated measuring tape.	Pharmadevils
2.	Check for the receipt of the consignment in good condition	Verified the consignment after receipt and found in intact condition.	Pharmadevils
3.	Check for any scratches on the machine body	No any scratch observed on equipment surface.	Pharmadevils
4.	Identify the hoppers with their lids	Lid observed over the hopper.	Pharmadevils
5.	Identify the Feed Frame in the working zone	Feed frame is at the working height.	Pharmadevils
6.	Identify the Feeding tube	Feeding tube found intact.	Pharmadevils
7.	Check for the electrical panel. All Electrical connections should be as per the Circuit Diagram.	All electrical connections found as per the circuit diagram available at electrical panel.	Pharmadevils
8.	Check driving component in base cabinet.	Driving component found at the base cabinet.	Pharmadevils

Checked By (Production) Pharmadevils 01/01/25
Sign/Date: .....

Verified By (Quality Assurance) Pharmadevils 01/01/25
Sign/Date: .....

Inference:

Verified Installation Checks (Dimensions / intact condition of multi-mill during receiving / scratch over surface / lid over hopper / feed frame at working height / feeding tube found intact / Circuit diagram available) & observed all checks within the acceptance criteria.

Reviewed By (Manager QA) Pharmadevils 01/01/25
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	Hopper found located at the top of the machine.	Pharmadevils
2.	**Feed Hopper (All types)**	Working zone	Feed Hopper found at the working level.	Pharmadevils
3.	**Column**	Below discharge hopper	Column found below the discharge hopper.	Pharmadevils
4.	**Bearing Housing**	Between Bearing 30206 (above) & 30207 (Below)	Housing available for ball bearings.	Pharmadevils
5.	**Blades**	Attached to beater	Blades found attached to beater.	Pharmadevils
6.	**Screen**	Held by screen holding plate attached to stud	Screen found held by screen holding plate attached to stud.	Pharmadevils
7.	**Screen Holding Plate**	Held with stud	Screen holding plate held with stud.	Pharmadevils
8.	**Motor**	Positioned above the hopper at the top the machine	Motor found positioned above the hopper at the top of the machine.	Pharmadevils
9.	**Castor Wheel**	At the base	Castor wheel found at the base.	Pharmadevils
10.	**Gasket**	Surrounding hopper (charging & discharging)	Gasket available around the hopper.	Pharmadevils

Checked By (Production) Pharmadevils 01/01/25
Sign/Date: .....

Verified By (Quality Assurance) Pharmadevils 01/01/25
Sign/Date: .....

Inference:

Verified components & their locations found as per the provided approved Design Specification.

Reviewed By (Manager QA) Pharmadevils 01/01/25
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	Machine found supported on 04 numbers of castor wheel to keep machine leveled with ground.	Pharmadevils
Check direction of motor	• Forward should give Clock wise rotation. • Reverse to give Anti-clockwise rotation.	Forward movement of blades shows clockwise rotation. Reverse movement of blades shows anti clockwise rotation.	Pharmadevils
Check for grease cup on bearing housing	Bearing housing should be fully greased for lubrication. (Recommended grease is MOSIL BRB500).	Bearing housing found fully greased for lubrication.	Pharmadevils
Assembled Rotor & the blade.	• The scraper blades have to be in the lowest. • Blade should be fixed with their knife edge in forward direction.	The scraper blades found at the lowest. Blades found fixed with their knife edges in forward direction.	Pharmadevils

Checked By (Production) Sign/Date: ..... Pharmadevils 01/01/25

Verified By (Quality Assurance) Sign/Date: ..... Pharmadevils 01/01/25

Inference:

Verified Installation Checks like machine support, motor direction, motor lubrication, found as per the acceptance criteria.

Reviewed By (Manager QA) Sign/Date:..... Pharmadevils 01/01/25

8.4 MOC Verification List:

S.No.	PARTS NAME	MOC	OBSERVATION
1.	**Motor**	STD	Motor found of standard size
2.	**Column**	AISI 304	Column found of AISI304 after verification by using Molybdenum test kit
3.	**Base**	MS with AISI 304 CLADED	Base is of MS with AISI 304 cladded.
4.	**Bearing housing**	CI	Bearing housing are of Cast Iron.
5.	**SS Blades**	SS316	SS blades are of SS316 after verification by using Molybdenum test kit.
6.	**Perforated Screen (2mm)**	AISI 316	Perforated Screen are of 2 mm made of AISI316 after verification by using Molybdenum test kit.
7.	**Screen Holding Plate**	AISI 316	Screen holding plate is of AISI316 after verification by using Molybdenum test kit.
8.	**Holding Plate Supporting Bolt & Wing**	AISI 316	Holding plate supporting bolt & wing are of AISI316 after verification by using Molybdenum test kit.
9.	**Feeding Hopper**	SS316	Feeding Hopper is of SS316 after verification by using Molybdenum test kit.
10.	**Intermediate Hopper**	SS316	Intermediate Hopper is of SS316 after verification by using Molybdenum test kit.
11.	**Discharge Hopper**	SS316	Discharge hopper is of SS316 after verification by using Molybdenum test kit.
12.	**Castor Wheel**	Nylon	Castor Wheel is of Nylon.
13.	**Gasket**	White Food Grade Silicon	Gasket made of White Food Grade Silicon.
14.	**Teflon Rope**	Teflon	Teflon rope made of Teflon.
15.	**Control Panel**	AISI 304	Control panel made of AISI304 after verification by using Molybdenum test kit.
16.	**Push Button**	STD	Push button is of standard size.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MILL

S.No.	PARTS NAME	MOC	OBSERVATION
17.	'V' - Belt	STD. Rubber	"V" Belt is of standard size made of rubber.

Checked By (Production)
Sign/Date: ……

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

Inference:

Verified contact & non-contact parts by using Molybdenum Kit & observed all contact parts of SS316 (Red color shows for SS316 & Green color shows for SS304).

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

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MILL

8.5 Utility Verification List:

S.No.	UTILITY PARAMETER	SPECIFIED	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
1.	**Make**	"REMI"	"REMI"	Motor is of "Remi" make.	Pharmadevils
2.	**Voltage:**	415 ± 5%	415 ± 5%	Voltage is of 415 V.	Pharmadevils
3.	**HP**	3HP	3HP	Motor is of 3 HP.	Pharmadevils
4.	**RPM**	1410	1410	Motor runs at the RPM of 1410.	Pharmadevils
5.	**AMP**	4.7	4.7	Current observed 4.7 Ampere.	Pharmadevils

Checked By (Production) Pharmadevils 01/01/25
Sign/Date: .....

Verified By (Quality Assurance) Pharmadevils 01/01/25
Sign/Date: .....

Inference:

Verified Installation Checks like machine support, motor direction, motor lubrication, found as per the acceptance criteria.

Reviewed By (Manager QA) Pharmadevils 01/01/25
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.	Miniature Circuit Breaker provided to avoid any short circuit or overload.
Mechanical Guard	Mechanical guard for all rotating parts.	Mechanical guard provided for all rotating parts.
Joints	Welding of joints without any welding burrs.	Welding joints without any welding burrs.
Metal Parts	All the metal parts should be properly grounded without any sharp Edges.	All metal parts found properly grounded without any sharp edges.
Leveling and Balancing	Equipment should be properly balanced & leveled.	Multi-mill is 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.	Electrical wiring found as per approved drawing. Double earthing provided to control panel.
Noise Level	Below 80 db.	Noise level observed below 80 db.
Emergency Switch	Provided easy access position.	Emergency Switch provided is easily accessible.

Checked By (Production) Sign/Date: 01/01/25

Verified By (Quality Assurance) Sign/Date: 01/01/25

Inference:

Verification done for Safety related features like proper fitting of Multi-mill, its electrical wirings, Guards for moving parts & Switch for ON & OFF during Emergency, all safety features found within the acceptance criteria.

Reviewed By (Manager QA) Sign / Date: 01/01/25

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MILL

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:

All Installations checks verified and observed as per approved Design Specification, no Deviation observed from the pre-defined acceptance criteria.

12.0 CHANGE CONTROL, IF ANY:

No any Change Control initiated during the Installation Verification; all checks were found as per the Design Specification.

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

Reviewed all Installation Checks (Leveling of Sifter / grinding of sharp edges / Welding joints / Illumination in area of Installation / working space / Equipment make & model / its components / Electrical fittings / MOC of Components / Dimensions & Safety features), all checks verified were found within the acceptance criteria, hence no any follow up action required.

14.0 CONCLUSION:

On the basis of above review, it can be concluded that all the Installation Checks were verified and observed as per the Design Specification provided to vendor and physically verified during FAT done by the site.

15.0 RECOMMENDATION:

On the basis of the above conclusion, the Installed Multi-mill shall be forwarded for Operational Qualification to find out the mechanical working of the Multi-mill.

16.0 ABBREVIATIONS:

AISI	:	American Iron and Steel Institute
CI	:	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

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MILL

17.0 PROTOCOL POST- APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)	QA Executive	Pharmadevils	02/01/25

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)	Head Production	Pharmadevils	03/01/25
HEAD (ENGINEERING)	Head Engineering	Pharmadevils	04/01/25

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)	Head Quality Assurance	Pharmadevils	06/01/25