OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

MULTI MILL

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

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MILL

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OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MILL

1.0 PROTOCOL CUM REPORT 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

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2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Multi Mill and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this Operational Qualification protocol cum report is limited to qualification of **Multi Mill** (**Make- Elicon Pharma)** installed in the **……..**
- 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 Protocol will define the methods and documentation used to perform OQ activity the Multi Mill for OQ. Successful completion of this Protocol will verify that Multi Mill meet all acceptance criteria and ready for Performance Qualification

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 Operational Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification. • Monitoring of Operation Process. • Post Approval of Operational Qualification Protocol cum Report after Execution
Production	• Review of Operational Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operation Qualification study as per Protocol. • Post Approval of Operational Qualification Protocol cum Report after Execution
Engineering	• Review & Pre Approval of Operational Qualification Protocol cum Report. • Co-ordination, Execution and technical support in Multi Mill Operational Qualification Activity. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Operational 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.	-
Supplier's Name	Elicon Pharma
Location of Installation	Granulation Area

6.0 EQUIPEMENT 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 750/1500/2100/3000 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 Verification of Documents:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- SOP for Operation & Cleaning of Multi Mill.
- SOP for Preventive Maintenance of Multi Mill.

7.1.1 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 OQ Protocol cum report.

7.1.2 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 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents.

Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No.	DOCUMENT NAME	DOCUMENT / SOP NO.	COMPLETED (YES/NO)	CHECKED BY (ENGINEERING) SIGN/DATE	VERIFIED BY (QA) SIGN/DATE
1.	DQ Protocol Cum Report	-	Yes	Pharmadevils 01/01/25	Pharmadevils 01/01/25
2.	IQ Protocol Cum Report	-	Yes	Pharmadevils 01/01/25	Pharmadevils 01/01/25
3.	SOP for operation & Cleaning of Multi Mill	-	Yes	Pharmadevils 01/01/25	Pharmadevils 01/01/25
4.	SOP for Preventive Maintenance of Multi Mill	-	Yes	Pharmadevils 01/01/25	Pharmadevils 01/01/25

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

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

Inference:

Verified & reviewed above mentioned documents for any deviation, change control or incident, no any such case observed prior commencement of Operational Qualification.

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

8.2 Test Equipment Calibration:

Verify that all critical instruments associated with the system will be in a calibrated state. Review the calibration status for the test equipment to be utilised and record the calibration due dates in the table below. All Equipment / Instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

EQUIPMENT / INSTRUMENTS NAME	EQUIPMENT / INSTRUMENT ID	CALIBRATION ON	DUE ON	OBSERVED BY SIGN/DATE
Tachometer	-	-	-	Pharmadevils

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

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

Inference:

All critical instruments associated with Multi-mill found calibrated (Tachometer used for RPM verification of blades).

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

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8.3 Operational and Functional Checks:

Operate the Multi Mill as per Manufacturer's Manual / SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

ITEM	OPERATION	ACCEPTANCE CRITERIA	OBSERVATION
Power supply	Connect 3Ph, 415V, AC supply to the control panel through proper isolator.	Machine will be ready for operation.	Power supply connected to the control panel through proper Isolator.
Motor & drive	Check the direction of motor shows on machine by direct arrow.	Motor should not run in opposite direction as arrow shows.	Motor when started runs in clockwise direction.
VFD	Run the motor at different speed.	Motor can be allowed to run at variable speed.	Variable Frequency Drive helps the motor to run in different speed.
Earthing	Proper earthing should be provided to machine.	Earthing will secure from shocks to operator of machine.	Proper earthing provided to avoid any electric shock to Operator.
Blades	• Check that blades should be properly tightened. • Check the blade should be properly fitted so no material leakage will occur from sides of the screen.	• If not then noise level will be more & also the possibility of removing blade. • For proper milling.	Blades found properly tightened & fitted, no any leakage observed from sides of screen, no any abnormal noise observed.
Bearing House	It will hold the blade assembly with shaft with the help of bearing for easy & smooth operation.	Proper lubrication should be done on bearing for noise free operation.	Food grade lubricant used for lubrication of bearings for noise free operations.
PU Wheel	For easy shifting of the machine.	Smooth handling & easy handling can be done.	Polyurethane Wheels installed for smooth handling & movement.

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

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

Inference:

Multi-mill operated as per the manufacturer's manual; all operating parameters found within the acceptance criteria during verification.

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

8.4 Safety Testing / Interlocking:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
To deactivate the equipment in event	The machine should stop immediately and should not start when started till emergency stop switch is released	Machine immediately stops when emergency stop switch is released.	Pharmadevils 01/01/25
Off an emergency stop	The machine should be made to turn off during any emergency.	Emergency stop used to switch OFF during emergency.	Pharmadevils 01/01/25

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

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

Inference:

Emergency Switch button pressed to switch OFF the Multi-mill in case of any emergency.

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

8.5 Power Failure Verification:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Main Power Shut Down	Equipment stops in a safe and secure condition.	As the main power shut down, the multi-mill stops in a safe and secure condition.	01/01/25
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.	As the main power restored, the Multi-mill restarted.	01/01/25

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

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

Inference:

Power failure verification done, equipment stops in safe mode when main power shut down and restarted when power restored.

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

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:

- Operation And Maintenance Manual
- Any Other Relevant Documents

11.0 DEVIATION FROM PREDEFINED SPECIFICATION, IF ANY:

All Operating parameters are found within the acceptance criteria, no any deviation observed from the pre-defined acceptance criteria.

12.0 CHANGE CONTROL, IF ANY:

Multi-mill was found as per the approved design, no any Change Control initiated for the same.

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

Reviewed all operating parameters, all were found within the acceptance criteria, no any follow up action required.

14.0 CONCLUSION:

On the basis of above review, it can be concluded that all the operating parameters (like motor operation / castor wheels movements / Interlockings to avoid equipment movement) of Multi-mill have been verified and found within the acceptance criteria.

15.0 RECOMMENDATION:

On the basis of above conclusion, the Multi-Mill Installed & Operated as per the approved DQ, IQ & OQ specifications, hence forwarded for the Performance Qualification.

16.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
IQ	:	Installation Qualification
mm	:	Millimeter
MML	:	Multi Mill
No.	:	Number
OQ	:	Operational Qualification
QA	:	Quality Assurance
SOP	:	Standard Operating Procedure
WHO	:	World Health Organization

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