



**PERFORMANCE QUALIFICATION
PROTOCOL
FOR
MULTIMILL**

EQUIPMENT No.:

Protocol No.	
Supersedes	
Effective Date	
No. of Pages	20



PERFORMANCE QUALIFICATION PROTOCOL FOR MULTI MILL

PROTOCOL CONTENTS

S.No.	Section Title	Page No.
1.0	Protocol Approval	3
2.0	Overview	4
	Objective	
	Purpose & Scope	
	Responsibility	
3.0	Training Record	5
	Purpose	
	Scope	
	Topics	
4.0	Qualification Requirements	6
5.0	Equipment Description	7-8
6.0	Qualification procedure	9
7.0	Acceptance Criteria	10
8.0	Qualification Report	10
9.0	Approval of Qualification Report	10
10.0	Qualification Criteria	10
11.0	Observed Deviation	11
12.0	List of Exhibits / Annexure	12
13.0	Reference Documents	12



PERFORMANCE QUALIFICATION PROTOCOL FOR MULTI MILL

1.0 Protocol Approval

This is a specific protocol for qualification of Multimill (**Equipment No.:**) which is installed in Plant.

This protocol shall be approved by the following:

Prepared By:

Name	Designation	Department	Signature	Date

Checked By:

Name	Designation	Department	Signature	Date

Approved By:

Name	Designation	Department	Signature	Date



PERFORMANCE QUALIFICATION PROTOCOL FOR MULTI MILL

2.0 Overview

2.1 Objective

To provide a documented evidence that the qualification of Multimill (**Equipment No. –**) has been performed as per the approved protocol.

2.2 Purpose and Scope

The purpose of the protocol is to demonstrate that the Multimill installed in Plant shall operate reproducibly and consistently within its full dynamic range of operation according to Functional /Manufacturers/In house specifications.

The scope of this qualification exercise is limited to the Qualification of Multimill (**Equipment No.**) of Plant.

2.3 Responsibility

- **Protocol / Report Preparation:** Quality Assurance (QA) Executive.
- **Protocol / Report Preparation:** Manager Production / Manager Engineering /
Manager Quality Assurance (QA).
- **Approval of Protocol / Report:** Head QA.

2.4 Qualification Team

- Production Executive/Officer/Manager
- Project Engineer /Manager
- Quality Assurance Executive/Manager

3.0 Training Record

3.1 Purpose



PERFORMANCE QUALIFICATION PROTOCOL FOR MULTI MILL

The purpose of this training is to familiarize the trainees with the overall strategy of Qualification of Multimill (**Equipment No.**), Plant.

3.2 Scope

This Training is applicable to Multimill (**Equipment No.**).

3.3 Topics

The following topics shall be covered during training:

- Principle of working of equipment.
- Overall strategy of Qualification process.
- General precautions / guidelines to be followed during qualification.

Note:

- *Training record shall be attached with the report as Annexure – 01*



PERFORMANCE QUALIFICATION PROTOCOL FOR MULTI MILL

4.0 Qualification Requirements

Following instruments shall be required for the Qualification of Multimill (**Equipment No.**) at Plant.

S.No.	Instrument Name	Instrument Code / S. No.	Calibration Certificate No.	Calibration Due On
1.	Tachometer			

Calibration certificates of master instruments shall be attached as **Annexure No-02.**



PERFORMANCE QUALIFICATION PROTOCOL FOR MULTI MILL

5.0 System / Equipment Description

5.1 System / Equipment details

The Multimill (**Equipment No.**) shall be used to reduce particle size of solid material of different active pharmaceutical ingredients in a homogeneous manner or appropriate milling as per process requirement.

Description

- Equipment Tag Number :
- Location : Plant (Ground Floor)
- Name of the system : Multimill
- Manufacturer's Name / Address : M/s
- Model : GMP
- Dimensions
 - Height : 2010 mm
 - Width : 850 mm
 - Length : 875 mm
- Capacity : 50 to 250 Kg/Hr.



PERFORMANCE QUALIFICATION PROTOCOL FOR MULTI MILL

5.2 Generic Design

5.2.1 Working Principle

Multimill is designed for getting particle size reduction through impact and pulverization of the material by blades moving at high speeds inside a cylindrical hopper. The milled particles pass through the screen placed inside the hopper and gets discharged through the discharge hopper.

5.2.2 Brief Machine Description

All Contact parts like Chamber, Blades, Screen, Charging hopper, Discharging hopper, Beaters are made of SS-316. Besides this all the parts of Multimill have easy access for cleaning. The drive mechanism is provided by an electric motor (3 HP, FLP) through a cone pulley arrangement. The drive is enclosed in an S.S. cover. Rotor has swinging type blades (knives - 12 Nos.) and scrapper blades (2 Nos.).

5.3 Safety feature Description

5.3.1 All corners rounded off

All corners shall be rounded for the personnel safety of the human being to avoid any accidentals cut during operation.

5.3.2 All electrical components are guarded

All electrical components are suitably guarded to restrict approach of personnel.



PERFORMANCE QUALIFICATION PROTOCOL FOR MULTI MILL

6.0 Qualification Procedure

Following procedure shall be used for the qualification of the Multimill (**Equipment No.**) installed in Plant.

- 6.1 The power supply and connected utility shall be checked. The details shall be recorded as per **Exhibit – E01**.
- 6.2 The operating functions of control panel switches and buttons shall be checked. The observations shall be recorded as per **Exhibit –E02**.
- 6.3 The Motor functioning test shall be performed. The observations shall be recorded as per **Exhibit - E03**.
- 6.4 The Multimill shall be subjected to blank trial and the results shall be recorded. The Multimill shall be run for 30 minutes and the observations shall be recorded as per **Exhibit- E04**.
- 6.5 Qualification checks shall be performed to verify that Multimill has been installed with proper electrical connections and utilities. The observations shall be recorded as per **Exhibit –E05**.
- 6.6 Any deviation observed during Qualification shall be recorded in the observed deviation, corrective action and justification report section.
- 6.7 Observed deviation shall be reported to the department head and quality head.
- 6.8 If the observed deviation does not have any major impact on the qualification, the final conclusion shall be provided.

If the observed deviation has major impact on the qualification, deviation shall be reported to the manufacturer for the corrective action and qualification activity shall be performed again.

7.0 Acceptance Criteria

Qualification shall be considered acceptable when requirements listed in section 6.0 of this document has been fulfilled.



PERFORMANCE QUALIFICATION PROTOCOL FOR MULTI MILL

8.0 Qualification Report

This report shall include the related documents and attachments / annexure which were completed at the time of qualification activity.

9.0 Approval of Qualification Report

The qualification report shall be evaluated and finally approved by Head Quality Assurance.

10.0 Qualification Criteria

- Location of the equipment
- The design of the equipment
- Major part of the equipment
- Regulatory requirement, or
- Equipment is replaced with new one.

The above changes shall be done through change control procedure.



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11.0 Observed Deviation

S. No	Page No.	Point No.	Observed Deviation	Deviation Reported By	Deviation Approved By	Corrective Action Taken	Justification of Corrective Action	Corrective Action Taken and Justification Given By	
Report Approved By									
Department Head						Quality Head			



PERFORMANCE QUALIFICATION PROTOCOL FOR MULTI MILL

12.0 List of Exhibits / Annexure

11.1 List of Exhibits

Exhibit No.	Exhibit Title	No. of Pages
E01	Power supply & connected Utilities Verification Check list	01
E02	Control Panel Interface Operation Verification	02
E03	Motor Functioning Test	01
E04	Equipment Performance Record (Blank trials)	02
E05	Checklist for Qualification	01
Total No of Pages		07

12.1 List of Annexure

Annexure No.	Annexure Title
E01	Training Record
E02	Calibration Certificates of Master Equipments

13.0 Reference Documents

13.1 Test certificates of components



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Exhibit – E01

Power Supply & connected Utilities Verification Check List

Equipment Name / Description : Multimill

Equipment No. :

Location : Plant

Date:

Time:

S.No.	Utility Description	Specifications	Actual Observations
1.	Power Supply		
	Voltage	395-435 Volts	
	Phase	3 Phase	
	Cycles	48 - 52 Hz	

Remarks:

Checked By: _____
(Name) (Sign) (Date)

Verified By: _____
(Name) (Sign) (Date)



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Exhibit – E02

Control Panel Interface Operation Verification

Equipment Name / Description : Multimill

Equipment No. :

Location : Plant

Date:

Time:

S.No.	Item	Action	Expected Result	Pass / Fail
1.	Green Push Button On	Push the button	The Green color switch shall glow & machine shall start.	
2.	Red Push Button Off	Push the red switch	The Machine shall stop	
3.	Red Color Switch On/Off	Turn the switch to ON position	All the light indications shall glow when the power is On.	
		Turn the switch to OFF position	All the light indications shall turn off when the power is Off.	
4.	Green Push Button On	Push the button	The Machine shall run in clockwise direction.	
	Yellow Push Button On	Push the button	The Machine shall run in anti - clockwise direction.	

Remarks:

Checked By: _____
(Name) (Sign) (Date)

Verified By: _____
(Name) (Sign) (Date)



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Exhibit – E03

Motor functioning Test

Equipment Name / Description : Multimill

Equipment No. :

Location : Plant

Date:

Time:

S.No.	Item	Action	Expected Result	Pass / Fail
1.	General Functioning (Check Direction Of Motor)	Check the motor functioning while motor is ON.	The motor shall run without any unwanted noise & without objectionable vibration (Motor Direction should Be clockwise)	
2.	Motor RPM	RPM shall be measured by attaching tachometer on the center of the shaft of motor	150 ± 10%	
			1440 ± 10%	

Remarks:

Checked By: _____
(Name) (Sign) (Date)

Verified By: _____
(Name) (Sign) (Date)



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Exhibit – E04

Equipment Performance Record (Blank trials)

Equipment Name / Description : Multimill

Equipment No. :

Location : Plant

Date: Time:

S.No.	Operation	Activity Performed	Expected Result	Pass / Fail
1.	Run the Multimill for 30 Minutes	Push the Green Button for rotation in clockwise direction	No Abnormal sound & Vibration shall be observed in the Equipment	
		Push the yellow Button for rotation in anti- clockwise direction	No Abnormal sound & vibration shall observed in the Equipment	

Remarks:

Checked By: _____
(Name) (Sign) (Date)

Verified By: _____
(Name) (Sign) (Date)



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Exhibit – E05

Checklist for Re-Qualification

Equipment Name / Description : Multimill

Equipment No. :

Location : Plant

Date: Time:

S.No.	Checks to be performed	Specifications	Actual observation
1.	Electrical connection	No loose connection shall be there	
2.	Levelling of Machine	Shall be Levelled properly	
3.	Belt Condition	Check the belt physically for cracks or worn out surface by rotating the drive	
		Check the tension of belt	
4.	Bolts	Check all the bolts, if loose tight it.	
5.	Main shaft lubrication	Open the bearing housing side covers and do the greasing	



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PERFORMANCE QUALIFICATION PROTOCOL FOR MULTI MILL

S.No.	Checks to be performed	Specifications	Actual observation
6.	Safety Guard	Check that safety guard is provided	
7.	Abnormal Sound/Vibration	Run the machine and check for any unusual sound/vibration	

Remarks:

Checked By: _____
(Name) (Sign) (Date)

Verified By: _____
(Name) (Sign) (Date)



PERFORMANCE QUALIFICATION PROTOCOL FOR MULTI MILL

Annexure – 01

Training Record

Equipment Name:	Multimill
Equipment No.:	
Location:	Plant
No. of Pages:	01



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PERFORMANCE QUALIFICATION PROTOCOL FOR MULTI MILL

Annexure – 02

Calibration Certificates of Master Instruments

Equipment Name:	Multimill
Equipment No.:	
Location:	Plant
No. of Pages:	01