DESIGN QUALIFICATION

PROTOCOL CUM REPORT

FOR

MULTI MILL

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MILL

PROTOCOL CONTENTS

DESIGN 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)			

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MILL

2.0 OBJECTIVE:

- To prepare the Design Qualification document for Multi Mill on basis of URS and information given by Supplier.
- To ensure that all Critical Aspects of Process/Product Requirement, cGMP and Safety have been considered in designing the equipment and are properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of **Multi Mill (Make: Elicon Pharma)** to be installed in **……..**
- Equipment Transfer from …….
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & IDs provided by Vendor shall be verified during Design 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 and Approval of the Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity. • Review of Design Qualification Protocol cum Report after Execution.
Production	• Review of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Design Qualification Protocol cum Report after Execution.
Engineering	• Review of the Design Qualification Protocol cum Report. • Assist in the Preparation of the Protocol cum Report. • To co-ordinate and support the Activity. • To assist in Verification of Critical Process Parameter, Drawings, as per the Specification i.e. ➢ GA Drawing ➢ Specification of the sub-components/ bought out items, their Make, Model, Quantity and backup records / brochures. ➢ Details of utilities ➢ Identification of components for calibration ➢ Material of construction of all components ➢ Brief Process Description ➢ Safety Features and Alarms • Review of Design Qualification Protocol cum Report after Execution.

5.0 PROJECT REQUIREMENTS:

To confirm that safe delivery of the equipment from the supplier site. To ensure that no un-authorized or unrecorded design modification shall take place.

If at any point in time, any change is desired in the mutually agreed design, change control procedure shall be followed and documented.

6.0 BRIEF EQUIPMENT DESCRIPTION:

Milling is an important step in pharmaceutical manufacturing process. This equipment is a self contained & portable unit for the process of size reduction. It uses the principle of impact of air. The product is dropped axially from the hopper in a communication chamber where it comes in contact with blades (either the knife edge or the impact edge) rotating at high speed.

Multi Mill is basically an acceleration type miller where the powders milled are subjected to acceleration force created by centrifugal force and gravity. Multi Mill is used for rapid milling of dry and semi – dry products. The central portion of the Multi Mill is provided with unique designed blades. Top portion of the machine is provided with feeder for material feeding. The milling is accomplished quickly and with most products within few minutes.

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MILL

7.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared…….. The manufacturer of equipment ensures complies with User Requirement Specification.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 EQUIPMENT PARAMETERS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Application: The Multi Mill should be able to mill various products.	Multi Mill machine should meet the requirement for rapid milling of dry and semi dry products.	Process Requirement
Working: Working of Multi Mill	Multi Mill machine should be capable of milling of pharmaceuticals ingredients.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

8.2 UTILITIY REQUIREMENTS / LOCATION SUITABILITY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	The electrical system of the equipment shall be housed as per the cGMP and cGEP standards, with adequate safety. Electrical panel and electro pneumatic panel is to be installed in service area.	cGMP Requirement
Room Condition	Temperature and RH required as per requirement of product.	Process Requirement

8.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

S.No.	NAME OF THE COMPONENT	TECHNICAL SPECIFICATION
1.	**Equipment**	Multi Mill
2.	**S.No.**	EP/P&CHPL/MM-3HP/8/AUG/2014
3.	**Model**	GMP Model.
4.	**Electric motor**	Make : Remi HP : 3HP RPM : 1410 Volt : 415 ± 10% Amp : 4.7 Type- : Flange Mounted Sr.No : 1CG-1347
5.	**'V' - Belt**	B-44
6.	**Out Put**	50 to 200 Kg /Hr.
7.	**Overall dimension (mm)**	900L X 800W X1700H in mm
8.	**Case Dimension (mm)**	1250 L X 1120W X2000H
9.	**Blade**	Impact/ Knife Edges 14 Nos.
10.	**Net Weight**	300 Kg (Approx)
11.	**Speed Available**	Should be capable of operating speed ranges: • 7500 RPM • 1500 RPM • 3000 RPM
12.	**VFD**	• Make – " ABB" • HP -3 HP
13.	**Spare Parts**	• Taper Roller Bearing • Gasket For Discharge Hopper • Gasket For Chute • Gasket For Charging Hopper

S.No.	NAME OF THE COMPONENT	TECHNICAL SPECIFICATION
14.	**Safety Features**	• Proper and effective earthing to the equipment. • All moving parts complete box type intact (Chain, gear box, motor etc.).
15.	**Castor wheel**	• Revolving brake type -2 Nos. –P.U. • Fix Type -2Nos. P.U.

8.4 MATERIAL OF CONSTRUCTION:

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

8.5 SAFETY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
MCB	MCB is provided so that when there is an overload in current or any short circuit then the MCB trips.	Safety Requirement
Mechanical Guard	Mechanical guard for all rotating parts.	Safety Requirement
Joints	Welding of joints without any welding burrs.	Safety Requirement
Metal Parts	All the metal parts should be properly grounded without any sharp Edges.	Safety Requirement
Leveling and Balancing	Equipment should be properly balanced & leveled.	Safety Requirement
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.	Safety Requirement
Noise Level	Below 80 db.	Safety Requirement
Emergency Switch	Provided easy access position.	Safety Requirement

8.6 VENDOR SELECTION:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Selection of Vendor for supplying the Multi Mill machine.	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical knowhow, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

Reference: (1) The equipment shall confirm to the specifications and requirement as URS.

(2) Operating and service manual for Multi Mill.

9.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- GA Drawing of multi Mill.
- Any other relevant documents

10.0 REVIEW

11.0 LOW UP ACTION, IF ANY):

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12.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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13.0 RECOMMENDATION:

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14.0 ABBREVIATIONS:

AISI	:	American Iron and Steel Institute
C.I.	:	Cast Iron
cGEP	:	Current Good Engineering Practice
cGMP	:	Current Good Manufacturing Practice
db	:	Decibel
DQ	:	Design Qualification
GA	:	General Arrangement
HP	:	Hours Power
Hr	:	Hour
kg	:	Kilogram
Ltd	:	Limited
MCB	:	Miniature circuit breaker
mm	:	Millimeter
MML	:	Multi Mill
MOC	:	Material of Construction
OD	:	Oral Solid Dosage
P & ID	:	Piping and Instrumentation Diagram
PO	:	Purchase Order
Pvt	:	Private
QA	:	Quality Assurance
RH	:	Relative Humidity
RPM	:	Revolution Per Minute
SS	:	Stainless Steel
URS	:	User requirement specification

15.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			