DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR COLLOID MILL

DESIGN QUALIFICATION

PROTOCOL CUM REPORT

FOR

COLLOID MILL

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

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR COLLOID MILL

1.0 PROTOCOL PRE-APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

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2.0 OBJECTIVE:

- To prepare the Design Qualification document for Colloid 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 **Colloid Mill (Make: Chamunda Pharma Machinery Pvt. Ltd.,)**.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.

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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	• Preparation, Review and authorization of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Post Approval of Qualification Protocol cum Report after Execution. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity.
Production	• Review of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Post Approval of Qualification Protocol cum Report after Execution
Engineering	• Review of the 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. ➢ 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 • Post Approval of Qualification Protocol after Execution.

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5.0 BRIEF EQUIPMENT DESCRIPTION:

Colloid mill is suitable for homogenizing, emulsifying, dispersing, mixing and comminuting of liquid to highly viscous products. It is based on rotor- stator principle. It is available in plain as well as water jacketed model which are suitable for heat sensitive products.

Three way cock system for drainage & recirculation of liquids provided as standard. Extra discharge spout provided as a standard for viscous products.

Special design facilitates adjustment of the grinding gap by an exterior screw by means of handle even during operation.

Colloid 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 rotating at high speed.

Operation:

Product is fed to the operating area of a rotor, having a speed of 2800 RPM by specially designed feed device. The product is processed by high shear, pressure & friction between the stator & rotor, and s also subjected to intense vibration, which exerts their force on it by means of pressing & releasing action. Due to the slightly deviating tapering of the milling surface of stator & rotor, the angular gap becomes narrow towards the discharge section.

6.0 EQUIPMENT SPECIFICATION:

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

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7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS / PRODUCT PARAMETERS:

Critical Variables	Acceptance Criteria	Reference
Application: The Colloid Mill should be able to mill various products.	Colloid Mill machine should meet the requirement.	Process Requirement
Working: Working of Colloid Mill	Colloid Mill machine should be capable of milling of pharmaceuticals ingredients.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

7.2 UTILITIY REQUIREMENTS / LOCATION SUITABILITY:

Critical Variables	Acceptance Criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	KW/HP : 2.2/3 Supply : 415 V, 3 Phase AC, 50 Hz	cGMP Requirement
Room Condition	Temperature and RH required as per requirement of product.	Process Requirement
Water Requirement	Water is required as per the packing process.	Process Requirement

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7.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

Critical Variables	Acceptance Criteria	Reference
Model No.	CPMCM-3	Design Requirement
S.No.	……..	Design Requirement
Hopper capacity	15 Ltrs.	Design Requirement
overall dimension	850 mm X 440 mm X 1410 mm	
Particle Size	5 to 10 microns.	Design Requirement
Design Capacity	Max Output: 12000 Kg/ Shift Min Output : 120 Kg/ shift	Design Requirement
Charging Height	1410 mm	Design Requirement
Discharging Height	750 mm	Design Requirement
Main Motor	Make : Hindustan Motor speed : 2800 RPM (±10%) Supply : 415 V,3Phase AC,50 Hz Type : Flange mounted, TEFC Frame : 90 L KW/HP : 2.25/3	Design Requirement
FLP Starter	Make : FCG Hp : 3 Relay : 4 to 6 amp	Design Requirement
Castor Wheel	Make : Swift Size : 65 x 25mm Model : SSPU6525M	Design Requirement
Application	Colloid Mill is Suitable for Homogenizing, Emulsifying, Dispersing, and Mixing Comminuting of Liquids to Highly Viscous Products.	Process Requirement

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7.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material Of Construction
1.	Housing	SS316
2.	Discharging Disc	SS316
3.	Rotor	SS316
4.	Cap On Rotor	SS316
5.	Center Bolt	SS316
6.	Upper Stator	SS316
7.	Lower Stator	SS316
8.	Baffle	SS316
9.	Hopper Cone	SS316
10.	3 Way Cock Assembly	SS316
11.	Mid Pipe	SS316
12.	Circulating Pipe	SS316
13.	Drain Pipe	SS316
14.	Cock Handle	SS304
15.	Discharge Hopper	SS316
16.	Hopper Lid	SS316
17.	Body Cover	SS304
18.	Top Cover	SS304
19.	Motor Housing	C.I.
20.	Base For Housing	C.I.

7.5 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

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7.6 VENDOR SELECTION:

Critical Variables	Acceptance Criteria	Reference
Selection of Vendor for supplying the Colloid 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: The equipment shall confirm to the specifications and requirement as specified in PO and URS.

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

8.0 DOCUMENTS TO BE ATTACHED:

- Any other relevant documents

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

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10.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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11.0 RECOMMENDATION:

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12.0 ABBREVIATIONS:

CFR	:	Code of Federal Regulations
cGMP	:	current Good Manufacturing Practices
COL	:	Colloid mill
DQ	:	Design Qualification
EU	:	European Union
FDA	:	Food and Drug Administration
Hz	:	Hertz
mm	:	Millimeter
QA	:	Quality Assurance
SOP	:	Standard Operating Procedure
URS	:	User Requirements Specification
V	:	Volt
WHO	:	World Health Organization

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13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY CONTROL)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			