INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR COLLOID MILL

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EQUIPMENT ID. No.	
LOCATION	**Solution Preparation**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

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INSTALLATION 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)			

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR COLLOID MILL

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Colloidal Mill.
- 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:

- To verify the critical dimensions of the unit and record Serial Numbers / Model Number of critical Components.
- To verify that the correct hardware has been installed, system initializes correctly.
- To Calibrate Temperature and Pressure Measurements of Control System, Recorder, Gauges and Displays.

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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, Authorization and Compilation of the Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity.
Production	• Review & Pre Approval of Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Qualification Protocol after Execution.
Engineering	• Review & Pre Approval of Protocol cum Report. • Co-ordination, Execution and technical support in Colloidal Mill Installation Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Qualification Protocol after Execution

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5.0 EQUIPMENT DETAILS:

Equipment Name	Colloid Mill
Equipment ID.	
Manufacturer's Name	Chamunda Pharma Machinery Pvt. Ltd.,
Model No.	
S.No.	
Supplier's Name	Chamunda Pharma Machinery Pvt. Ltd.
Location of Installation	Solution Preparation

6.0 EQUIPMENT DESCRIPTION:

Colloidal 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.

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7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document
- Technical specification of equipment

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 IQ 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 Installation Qualification Checklist:

S.No.	Installation Check	Observation (Complies/ Not Complies)	Observed by (Engineering) Sign/ Date
1.	Check for the Dimensional accuracy		
2.	Check for the receipt of the consignment in good condition		
3.	Check for any scratches on the machine body		
4.	Check for the electrical panel. All Electrical connections should be as per the Circuit Diagram.		
5.	Check the Rotor Assembly Free Movements		
6.	Check The Grease in the Bearing Housing		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR COLLOID MILL

8.2 Technical specification:

S.No.	Component	Acceptance Criteria	Observation (Complies/ Not Complies)	Observed by Engineering (Sign/Date)
1.	Model No.	CPMCM-3		
2.	S.No.			
3.	Hopper	15 Ltr.		
4.	Particle size reduction	5 to 10 microns		
5.	Design capacity	Max output :12000 Kg/ shift Minimum output: 120 Kg/ shift		
6.	Charging Height	1410 mm		
7.	Discharging Height	750 mm		
8.	Over All Dimension	850 mm x 440 mm x 1410 mm		
9.	Main Motor	Make : Hindustan Motor speed (±10%) : 2800 RPM Supply : 415 V,3Phase,50 Hz Type : Flange mounted, TEFC Frame : 90 L KW/HP : 2.25/3		
10.	FLP Starter	Make : FCG Hp : 3 Relay : 4 to 6 amp		
11.	Castor Wheel	Make : Swift Size : 65 x 25mm Model : SSPU6525M		

Checked By
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Sign/Date: ……

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(Quality Assurance)
Sign/Date: ……

Inference:

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

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8.3 MOC Verification List:

S.No.	Component	MOC	Observation (Complies/ Not Complies)	Observed by Engineering (Sign/Date)
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.		

Checked By
(Production)
Sign/Date: ……

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8.4 SAFETY:

Critical variables	Acceptance criteria	Observation (Complies/ Not Complies)	Observed by Engineering (Sign/Date)
MCB	MCB is provided so that when there is an overload in current or any short circuit then the MCB trips.		
Mechanical Guard	Mechanical guard for all rotating parts.		
Joints	Welding of joints without any welding burrs.		
Metal Parts	All the metal parts should be properly grounded without any sharp Edges.		
Leveling and Balancing	Equipment should be 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.		
Noise Level	Below 80 db.		
Emergency Switch	Provided easy access position.		

Checked By
(Production)
Sign/Date: ……

Verified By
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Inference:

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

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
COLLOID 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:

- Any other relevant documents

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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12.0 CHANGE CONTROL, IF ANY:

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

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 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
IQ	:	Installation Qualification
mm	:	Millimeter
MOC	:	Material of Constructions
No.	:	Number
QA	:	Quality Assurance
SOP	:	Standard Operating Procedure
URS	:	User Requirements Specification
V	:	Volt
WHO	:	World Health Organization

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17.0 PROTOCOL POST-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)			