OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR COLLOID MILL

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

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR COLLOID MILL

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OPERATIONAL 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 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 Colloid 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 Colloid Mill installed in the Solution Preparation.
- This Protocol will define the methods and documentation used to perform OQ activity the Colloid Mill for OQ. Successful completion of this Protocol will verify that Colloid Mill meet all acceptance The Protocol covers all aspects of Operation Qualification for Colloid Mill.
- The Colloid 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.

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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, Approval and Compilation of the Operation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operation Qualification. • Monitoring of Operation Process.
Production	• Review & Pre Approval of Operation Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operation Qualification study as per Protocol. • Review & Post Approval of Operation Qualification Protocol after Execution
Engineering	• Review of Protocol cum Report. • Co-ordination, Execution and technical support in Colloid Mill Operational Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Review 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	
S.No.	
Supplier's Name	Chamunda Pharma Machinery Pvt. Ltd.
Location of Installation	Solution Preparation

6.0 EQUIPEMENT 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.

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7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- Executed and approved Installation qualification document.
- SOP for Operation & Cleaning of Colloid Mill.
- SOP for Preventive & Maintenance of Colloid 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 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 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 (Quality Assurance) Sign/Date
1.	DQ Protocol Cum Report				
2.	IQ Protocol Cum Report				
3.	SOP for operation & Cleaning of Colloid Mill				
4.	SOP for Preventive Maintenance of Colloid Mill				

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 I.D.	Calibration On	Due On	Observed By Sign / Date

Checked By
(Production)
Sign/Date: ……

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

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8.3 Operational And Functional Checks:

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

Item	Acceptance criteria	Observation (Complies/ Not Complies)	Observed By (Engineering) Sign/Date
Power supply	Connect 3Ph, 415V, AC supply to the control panel through proper isolator		
Motor & drive	Check the direction of motor shows on machine by direct arrow.		
ON-OFF Operation Push Button	Green Button Operation Starts &Red Operation Stops as Required		
Blades	• Check that blades should be properly tightened. • Check the blade should be properly fitted son on material leakage will occur from sides of the screen.		
Application	Colloid Mill is Suitable for Homogenizing, Emulsifying, Dispersing, and Mixing Comminuting of Liquids to Highly Viscous Products.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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8.4 Safety Testing / Interlocking:

Item	Acceptance Criteria	Observation (Complies/ Not Complies)	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		
Off an emergency stop	The machine should be made to turn off during any emergency.		
Alarm	To verify alarm function and respond according to the system design		
Noise Level	Below 80 db		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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8.5 Power Failure Verification:

Item	Acceptance Criteria	Observation (Complies/ Not Complies)	Observed By (Engineering) Sign/Date
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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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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FOR
COLLOID MILL

16.0 ABBREVIATIONS:

Amp.	:	Amper
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
COL	:	Colloid Mill
DQ	:	Design Qualification
FDA	:	Food and Drug Administration
HP	:	Horse power
ID.	:	Identification
IQ	:	Installation Qualification
Kg	:	Kilo gram
KW	:	Kilo watt
Ltrs	:	Liters
MCB	:	Miniature circuit break
mm	:	Millimeter
MOC	:	Material of construction
NLT	:	Not less than
No.	:	Number
OQ	:	Operational Qualification
QA	:	Quality Assurance
SS	:	Stainless steel
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)			