INSTALLATION QUALIFICATION

NAME OF THE ITEM: MULTIMILL

FUNCTIONAL AREA: DRY SYRUP

PROTOCOL No. :

CONTENTS

1.0 Protocol APPROVAL:

Prepared By:

Functional area	Name	Signature	Date
Engineering			

Reviewed By:

Functional area	Name	Signature	Date
Engineering			
Production			
Quality assurance			

Approved By:

Functional area	Name	Signature	Date
Head Engineering			
Head Manufacturing			
Head Quality			

2.0 Objective:

The purpose of this document is to provide an outline for the inspection of equipment for static attributes to verify that;

- The system is constructed according to the design specifications described in the Design Qualification.
- The system is installed according to the design specifications and manufacturer's recommendations.
- Each installed sub-component has been checked physically and verified the same in accordance with the approved design and equipment data sheets/ specifications.
- The system meets the current Good Manufacturing Practice (cGMP) & Safety requirements.
- No un-authorized or unrecorded modifications have taken place.

Instructions:

- For each data sheet, record the requested information in black ink.
- In the "Verified" column, indicate that the item is inspected and verified according to pre-laid Specifications. Verification can be by a visual examination referring literature and using a measuring device, etc.
- After each data sheet is completed, put signature and date in the assigned space.
- Where the required information is not available 'Not Available' shall be entered accordingly. A single diagonal line shall be scribed through unused boxes and comments sections and "N/A" meaning "not applicable" entered, along with initials and date of the person who enters the line.
- After installation, check all instruments and components are installed as per the P&ID. Use a copy of this diagram as checklist and after completion of checking, attach this verified copy duly signed and approved along with this report.
- After completion of installation vendor should issue the commissioning report, which has to be authenticated by the engineering department.

3.0 Responsibilities:

In accordance with protocol, following functions shall be responsible for the qualification of equipment regardless of whether such work is performed by own staff or contract / consulting staff. When the work is carried by contract/ consulting staff.

3.1 Engineering Department

- Prepares the Installation qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures on equipment Qualification.
- Ensures that the content is sufficient, clearly defined, technically sound and accurate.
- Ensures compliance with design specifications for equipment / system.
- Distributes the draft protocol for review and collates comments.
- Makes any necessary corrections to the protocol and answers queries from the reviewers.
- Distributes the finalized protocol for review and approval signatures.
- Execution of IQ protocol.
- Develop departmental SOPs, log books, where appropriate.
- Review of protocol, the completed qualification data package, and the final report.

3.2 Head/Designee Engineering, production and quality assurance

- Review of protocol and the completed qualification data package, and the final report.
- Assist in the resolution of validation deficiencies.

3.2 Head/Designee Engineering, Manufacturing and Quality

- Approval of protocol and the completed qualification data package, and the final report.
- Assist the equipment user in the execution of the protocol.
- Verification that the protocol test requirements are completed and properly documented for approval.
- Assist in the resolution of validation variances.

4.0 Equipment Description & Identification:

4.1 Scope:

For new installation, modification, replacement or relocation of any component of Multi mill.

Room name	Room No.	Equipment No.
Granulation		

4.2 Name of the Equipment : Multi mill

4.3 Make /Redesigned by : Chempro Pharamch Equipments

4.4 Model No. / TYPE : Multimill std

4.5 Serial No. :

4.6 Equipment Identification No.:

4.7 Equipment Location :

Remarks (if any)**:** _____

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Verified By & Date:

5.0 List of Reference Documents & Drawings:

Sr. No.	Name	Document number	Location	Checked by
01	User Requirement Specifications (URS)			
02	Purchase Order			
03	SAT Report			
04	Operating and Maintenance Manual			
05	P & I Diagram			
06	Mechanical Drawing			
07	Electrical Diagram			
08	General Arrangements / schematic line diagram			
09	Utility diagram			
10	Civil layouts			

Remarks (if any)**:** _____

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Verified By & Date:

6.0 Verification of Equipment on Receipt:

Sr. No.	Title	Observation	Checked by
1.	Purchase Order Number and date		
2.	Was the Machine Properly Protected From Heat, Rain & Dirt etc? During Transportation?		
3.	Physical verification of machine and its components for any damage		
4.	Nature of damage, if any		
5.	Corrective action in case of any damage.		
6.	Availability of accessories as per packing list received		

Remarks (if any)**:** _____

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Verified By & Date:

7.0 Verification of Major Components:

The principal components of the machine are listed in the following table. Visually inspect the components as installed and verify that it is as specified in the acceptance criteria.

Sr. No.	Name of Component	Specified	Observation	Checked by sign/date
1.	Bottom Plate	Chempro		
2.	Column	Chempro		
3.	Motor mounting plate	Chempro		
4.	Bearing Housing	Chempro		
5.	Housing Assembly unit	Chempro		
6.	Inlet Hopper	Chempro		
7.	Outlet hopper	Chempro		
8.	Hammering blades	Chempro		
9.	Cutting systems	Chempro		
10.	Caster wheel	swish		
11.	Mesh	chempro		
12.	Motor 3HP/1440RPM/50HZ	Hindustan		
13.	Control panel	Chempro		
14.	V-belt	Nerlom		

Remarks (if any)**:** _____

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Verified By & Date:

8.0 Physical Verification of Area:

Sr. No.	Title	Observation	Checked by
1.	Name of Room and Identification No, where the machine to be installed		
2.	Dimension of the equipment (As per Machine Drawing/ Manual)		
3.	Verify that there is sufficient space for easy movement of man and material after installation		
4.	Verify that foundation arrangement has been made for proper fixing of equipment		
5.	Equipment lifting and positioning arrangement		
6.	Verify that provisions for required utilities are provided.		
	Electricity		

Remarks (if any):

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Verified By & Date:

9.0 FAT Compliance

S.No	Observation	Verification	Remark

Remarks (if any):

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Verified By & Date:

10.0 Verification Of Installation:

Sr. No.	Description Of Machine Components	Acceptance criteria	Observations	Checked By & Date
1.	A process instruments diagram (P & ID).	All instruments and components shall be installed as per approved P & ID.		
2.	Horizontal leveling of the equipment	Should be perfectly horizontal		
3.	Positioning of the equipment	It should be aligned vertically straight. There should be enough space to open guards for maintenance purposes.		
4.	Floor balancing	No vibration at any corner of the equipment should be observed due to floor leveling problem.		
5.	Surface finish of equipment	Should be smooth & even.		
6.	Any physical damage to the equipment.	No physical damage should be observed.		
7.	General method of the electrical wiring	▪ No loose hanging cables ▪ Well-insulated electrical wirings. ▪ Located in a safe place and well protected.		

Remarks:_____

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Verified By & Date:

11.0 Verification of Special Features in The Equipment

11.1 Safety requirements:

Sr. No.	User requirement	Acceptance criteria	Observations	Checked By & Date
1.	Earthing	Touch the tester to body of machine bulb of tester should not glow		
2.	Emergency switch	Should be stop immediately		

Remarks (If any)**:** _____

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Verified By & Date:

11.2 Automation control and Electrical connections:

Sr. No.	User Requirement	Acceptance Criteria	Observations	Checked By & Date
1.	Motor	With Test Certificate		

Remarks (If any)**:**

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Verified By & Date:

12.0 Material of Construction:

List down and verify that the construction material of equipment components that come into contact with the product are as specified by the Manufacturer and satisfy the User Requirement. All certificates related to material of constriction should be attached.

Component	Specified	As Found	Confirmed by/ Evidence	Acceptable?	
				Yes/No	Initial & Date
Bottom Plate	M.S. CLADED with S.S. 304				
Column	S.S.304				
Motor mounting plate	M.S. CLADED with S.S. 304				
Bearing Housing	C.S.				
Housing Assembly unit	S.S. 316				
Inlet Hopper	S.S. 316				
Outlet hopper	S.S. 316				
Hammering blades	S.S. 316				
Cutting systems	S.S. 316				
Caster wheel	P.U. COATED				
Mesh	S.S. 316				
Control panel	SS 304				

Remarks (if any)**:** _____

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Verified By & Date:

13.0 Utilities/ Services Connection Check:

Verify the installed service connections to the component against the supplier's specification.

Utility	Specified	As Found	Confirmed by/ Evidence	Acceptable?	
				Yes/No	Initial & Date
Electricity	3 phase,50 htz,315v				

Remarks (if any)**:** _____

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Verified By & Date:

14.0 Manufacturer's Certificates:

Review and attach all manufacturers' certificate(s) as per DQ and also attach any other certificate.

Remarks (if any)**:** _____

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Verified By & Date:

14.1 Identification of Training Need For Operating Personnel:

Sr. No.	Training Title	Identified By & Date

Remarks (If any)**:**

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Verified By & Date:

15.0 Deficiency Sheet:

Report any deficiencies from the acceptance criteria or from protocol instructions in the deficiency report form of Appendix 1. Record the total number of deficiencies reported during the installation qualification activities of this Protocol. Record the deficiency number and Title in the Table below. Include all deficiency Report Forms in Appendix 1. Indicate the status of each variance as 'Closed' only when the deficiency is resolved.

Deficiency No.	Deficiency Title	Status

Total No. Of Deficiencies: _____

Remarks (If any)**:**

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Verified By & Date:

16.0 List of Appendix:

Appendix No.	Document Title

Remarks (If any)**:**

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Verified By & Date:

17.0 Deficiency and Corrective Action Report Form

This Deficiency and Corrective Action Report Form shall be completed for each result that does not meet the expected or as designed condition encountered during the execution of the protocol. Each form shall be numbered sequentially and tracked on the Deficiency Sheet within the protocol.

Deficiency Report Number:	
Protocol Section No.:	Date of Test:
Description Of Test Result:	
Immediate Action Taken:	
Corrective Action Taken / Planned:	
Deficiency Reported By: Name: Signature:	Date:
Corrective action must be taken prior to approval of IQ or OQ? :	
Head - Engg. Signature Date:	
Head-User dept. signature Date	
QA Signature:	Date:
<u>Corrective Action Implemented:</u>	
Corrective Action Implemented By: Name: Signature:	Date:
(Attach comments and supporting documentation as necessary)	
Was a re-test or amendment necessary due to the Deficiency?	Date of re-test:
Is Deficiency Closed (Yes/No):	
QA Signature:	Date:

18.0 Summary & Conclusion:

Prepared By: _____ _____

Name & Department Sign. / Date

19.0 Post Approval:

Functional Area	Name	Signature	Date
Head Engineering			
Head Manufacturing			
Head Quality			