OPERATIONAL QUALIFICATION PROTOCOL

NAME OF THE ITEM: MULTIMILL

FUNCTIONAL AREA: DRY SYRUP

PROTOCOL No. :

CONTENTS

1.0 Protocol Approval:

Prepared By:

Functional area	Name	Signature	Date
Production			

Reviewed By:

Functional area	Name	Signature	Date
Production			
Engineering			
Quality Assurance			

Approved By:

Functional area	Name	Signature	Date
Head Engineering			
Head Manufacturing			
Head Quality			

2.0 Objective:

The objective of this protocol is to provide an outline for the operation of equipment and to verify that;

- The equipment works in compliance with the functional requirements and to verify that the system performs in accordance with the system specifications throughout all pre-defined operating ranges.
- Document initial performance of the Equipment / System for future reference.
- The system meets the current Good Manufacturing Practice (cGMP) & Safety requirements.
- No un-authorized or unrecorded modifications have taken place.
- Finalization SOP
- Training of operators

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.

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 Production Team:

- Prepares the Operational 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 OQ protocol.
- Develop departmental SOPs, log books, where appropriate.

- Review of protocol, the completed qualification data package, and the final report.

3.2 Head /Designee: Production/Engineering/Quality Assurance.

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

3.2 Head/Designee: Engineering /Manufacturing/ Quality.

- Review and Approval of protocol, the completed qualification data package, and the final report.
- 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 and Purpose:

The purpose of this document is to provide an outline for the Operation of Multi mill.

Room name	Room No.	Equipment No.
Granulation-I		

4.2 Name of The Equipment : Multimill

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)**:** _____

_____

_____

Verified By & Date:

5.0 Methodology for Operational Qualification:

5.1 Before the operating the equipment, verify that the component(s) (identified during IQ), which are required calibration, have been calibrated.

5.2 Operate the equipment as per the draft Standard Operating Procedure (SOP), which is derived from recommendations given in manufacturers "Operating and Maintenance Manual".

5.3 Verify the operation of function of keys provided in the control panel of the equipment.

5.4 Verify the critical operating parameters are achieving and are in line with the design specifications.

5.5 Operate the equipment by operator(s), who is going to operate the machine in routine activities.

5.6 Verify the SOP(s) for the suitability. Review the draft SOP(s) its accuracy with the procedure to be followed in routine activities and finalize the SOP(s).

5.7 Modify the SOP, if there is any requirement for change(s).

5.8 Perform the trial with the revised SOP(s) and finalize the same.

Remarks (if any)**:** _____

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Verified By & Date:

6.0Test equipment/Instrument Calibration:

Prior to operational qualification, carry out calibration of all instrument(s) / measuring device(s), identified during Installation Qualification of the equipment.

Sr. No.	Instrument to be Calibrated	Location of Instrument	ID	Calibration Certificate No.	Calibration Date	Frequency	Checked By & Date

Remarks (if any)**:** _____

_____

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_____

Verified By & Date:

7.0 Safety Features Testing

Sr. No.	Safety Feature	Acceptance criteria	Result (Pass/ Fail)	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)**:** _____

_____

Verified By & Date:

8.0 Operational Testing

8.1 Alarm/Interlock Verification

Method of Testing	Acceptance Criteria	Observation	Checked by/ Date
1. EMERGENCY PRESSED			
Press Emergency Stop.	Machine will stop		
3. POWER FAILURE			
Switch OFF main panel.	Machine will stop		

Remarks (if any)**:**

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_____

Verified By & Date:

8.2 Functional Operation Verification

Method of Testing	Acceptance Criteria	Observation	Checked by/Date

Remarks (if any)**:**

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_____

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Verified By & Date:

9.0 SOP Verification:

Sr.No.	Subject	Sop No	Remarks	Checked By	Date
1.					
2.					
3.					

Remarks (if any)**:**

_____

_____

_____

Verified By & Date:

Contents of SOP:

Sr.No.	Check Point for SOP(s)	Observation	Checked by
1.	Individual responsibilities are defined properly		
2.	Verify that operations procedure is defined sequentially		
3.	Verify that adequate checklists and reporting formats are provided		
4.	Verify that, information provided in the SOP are sufficient		
5.	Verify that acceptance criteria are specified in the SOP		
6.	Verify that action plan is defined in case of any abnormal event		
7.	Verify that cleaning procedures are adequate (by visual inspection)		

Recommendation(s) / Status of SOP: _____

_____

_____

Verified By & Date:

10.0 Review of Training Imparted:

Sr.No.	Subject	Faculty	Trainee(s)	Date of Training

Remarks (if any)**:** _____

_____

_____

Verified By & Date:

11.0 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 operational 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)**:**

_____

_____

_____

Verified By & Date:

12.0 List of Appendix:

Appendix No.	Document Title

Remarks (If any)**:**

_____

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Verified By & Date:

13.0 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:
Corrective Action Implemented:
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:

14.0 Summary & Conclusion:

Prepared By: _____ _____

Name & Department Sign. / Date

15.0 Post Approval:

Functional Area	Name	Signature	Date
Head Engineering			
Head Manufacturing			
Head Quality Assurance			