OPERATIONAL QUALIFICATION

PROTOCOL

FOR

MULTIMILL

EQUIPMENT ID	
EQUIPMENT LOCATION	
EQUIPMENT MAKE`	**CHEMPRO PHARMACH EQUIPMENTS**
DOCUMENT NO.	
REASON FOR QUALIFICATION	**NEW EQUIPMENT**

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR MULTIMILL	PROTOCOL No.:

TABLE CONTENT

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR MULTIMILL	PROTOCOL No.:

1.0 PRE-APPROVAL

Signing of this Operational Qualification Protocol indicates agreement with the Validation Master Plan approach of the equipment. Further if any changes in this protocol are required, protocol will be revised and duly approved.

PREPARED BY:

Organization	Name	Signature	Date
Production			

CHECKED BY:

Organization	Name	Signature	Date
Engineering			
Production			
Quality assurance			

APPROVED BY:

Organization	Name	Signature	Date
Head Engineering			
Head Manufacturing			

2.0 OBJECTIVE:

The objectives of this Operational Qualification (OQ) are as follows:

- 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 demonstrate that the system will operate reproducibly and consistently within its operating range.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

Following execution of the protocol a summary report will be written and approved. All results, conclusions, exceptions and variances will be addressed and final disposition of the equipment will be multimill stated. Successful completion of this protocol and approval of the summary report will verify that the meets all the acceptance criteria and is ready for PQ.

3.0 SCOPE:

This protocol covers all aspects of Operational Qualification for the Multimill. Scope incorporates qualification of all Multimill components from Raw material loading into the feed hopper, feed chute, Rotor assembly with fixed beaters & screen upto discharge hopper.
This protocol will define the methods and documentation used to qualify the Multimill. Successful completion of this protocol will verify that the Multimill meets all acceptance criteria and is ready for Performance Qualification.

4.0 RESPONSIBILITIES:

The following are the responsibilities of Validation Personnel:

- Preparation, Review and submission of OQ Protocol.
- Ensures that the protocol is in compliance with current ALL policies and procedures.
- Ensures that the content is sufficient, clearly defined technically sound and accurate.
- Ensures compliance with design specifications.

The following are the primary responsibilities of the ALL Validation Personnel:

- Overall cGMP compliance for OQ
- Review and Pre-Approval of OQ Protocol
- Execution of this OQ protocol
- Document Control of OQ Protocol until such document is completed, approved and after.
- Regulatory Compliance Review of the completed OQ Protocol
- Review and Approval of the executed OQ Protocol.

5.0 SYSTEM DESCRIPTION

The Multimill and its associated equipment are designed to process pharmaceutical products in accordance with cGMP principles. Multimill can be used for particle size reduction depending upon product requirement.

Raw materials are loaded manually into the feed hopper of the Multimill for particle size reduction. After milling material is discharged through the discharge hopper into the IPC and send to the granulation suits for granulation.

Qualification activities for the Multimill incorporate the following system components:

- Feed Chute
- Rotor Assembly with fixed beaters
- Screen

Multimill is used for grinding of various dispensed ingredients. After milling material is discharged through the discharge hopper into the IPC and send to the granulation suits for granulation. System consists of feed chute, Rotor assembly with fixed beaters & screen. Beater is SS-316 hard chrome plated to reduce wear &tear. Base frame and wheel trolley is made of SS-304 with PU wheels. Ingress protection for all electrical components is IP-55 to ensure suitability for a dusty atmosphere. Base Belt guard is 360 degree covered and is SS-304 construction Screen is with 1.5 mm dia. round /square holes.

6.0 DOCUMENTATION REQUIREMENTS:

The OQ File should include:

- This OQ Protocol.
- Any laboratory test results or their referenced location.
- Any change control actions that may have occurred during the qualification activities.
- Any variances, exceptions or investigation reports generated during the qualification activities.

7.0 DATA COLLECTION:

All individuals executing this Protocol shall complete the attached Signature *Sheet.* All personnel shall have suitable documented training or experience.

All approvals shall be made in *BLACK* ink.

All data entry shall be made in *BLACK* ink.
All corrections to this Protocol, which are not retyped, are to be made in *BLACK* ink. All written corrections to this Protocol or to data entered in this Protocol should be made by using a single line to delete the error. The person who makes the correction shall initial and date it and add comment to explain reason for correction.
After performing the qualification tests, collect all relevant printouts and certificates and retain for inclusion in the OQ File. If more Data Sheets or Variance Sheets are required, they are to be attached to this Protocol as *Annexure* and to be listed in *Section 14 List of Annexure.*

8.0 CHANGE CONTROL:

Any changes or modifications to the system shall be performed in accordance with the ALL Project Change Control Procedure. Change Control Forms raised during the execution of this OQ will be filed along with the protocol. An assessment will be made for each change to determine whether or not any re-validation is required.

9.0 PRE-QUALIFICATION REQUIREMENTS:

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. Open action items resulting from these tests shall be listed in the Comments section.

9.1 System Pre-requisites

S.No.	Description of Pre-requisite	Completed [Yes / No]	Verified By	Date
1	Verify that the IQ of the Multimill has been executed and approved. IQ Protocol Document No:	Yes/No*		
2	Verify that Site Acceptance Tests (SAT) of the Multimill has been executed and approved.	Yes/No*		
3	Verify that the safety walk through has been completed and that the system is safe to use.	Yes/No*		
Verify that authorised drafts of the following procedures (SOP / PMI) relevant to operation of the Multimill are available.				
4	SOP of Multimill Operation	Yes/No*		
5	SOP of Multimill Maintenance.	Yes/No*		

Note:- * -Circle one, which is appropriate.

9.2 Test Equipment Calibration

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 Name	Equipment Owner	Equipment Number	Due Date	Signature	Date

Reviewed by		Date	

10.0 TESTS AND CHECKS:

10.1 SOP Verification

10.1.1 Purpose

To verify the accuracy of Standard Operating Procedures applicable to the Multimill.

10.1.2 Method

Obtain a controlled copy of each SOP referenced within section 10.1.4. During the course of OQ testing, perform each operation according to the instruction indicated within the appropriate SOP. Mark with a highlighter pen each instruction or statement within the SOP which is verified and in accordance with the actual practice. Write any differences from actual practice in red ink on the copy of the SOP. On completion, write "Operational Qualification - SOP Verification" on the marked-up copy of the SOP, sign & date it and attach as an annexure to the OQ protocol together with any other raw data such as printouts.
Ensure all SOP's identified in Section 10.1.4 are evaluated and checked.

10.1.3 Acceptance Criteria

At the completion of OQ testing, all standard operating procedures referenced within section 10.1.4 will be annotated to correctly reflect the applicable method instruction(s) required to obtain intended operation or function result.

10.1.4 Results

Enter the SOP's into the table below and verify that they have been evaluated and checked. Incorporate the marked up SOPs as an appendix to the OQ report together with any other raw data such as printouts

SOP Number	SOP Description	SOP accurate after check [Y/N]	Initial / Date
……..	Multimill Operation and cleaning		

Comments:

Reviewed by		Date	

10.2 System Start-Up and Shutdown Test

10.2.1 Objective

To verify that the system components will power-up and start as defined by the design documentation.

10.2.2 Method

Follow instructions in the Test Method column of section 10.2.4 to test the start-up and shutdown of each system component. Obtain approval from the Production, Electrical and Mechanical Departments (where applicable) prior to this test and attach the approval slip as an appendix to this protocol. Record all observations in section 10.2.4 and attach any raw data printouts as an appendix to this protocol.

10.2.3 Acceptance Criteria

All Start-up and Shutdown functions operate correctly as specified in the following document:

- *System Operating and Maintenance Manual* Multimill as supplied by vendor.

Specific acceptance criteria for each test are provided in the tables in section 10.2.4.

10.2.4 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Shutdown Procedure				
Operate rotor assembly Motor.	Rotor assembly stops.			
Switch “OFF” the mains on the control panel	“OFF” Indication in indicator.			
Power-Up and Start Test				
Switch ‘ON’ the mains on the control panel	“ON” Indication in indicator.			
Operate rotor assembly Motor.	Rotor rotates on desired RPM set in the VFD.			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.3 System Functionality Tests

10.3.1 Objective

To verify Multimill components functionality.

10.3.2 Method

Prior to this test, power up and start-up each component as described in Section 10.2.4: *Power Up and Start Test.* Operate each item as described in Section 10.3.4 to test the functionality of the system. Record all observations in the Actual Results column in Section 10.3.4.

10.3.3 Acceptance Criteria

All aspects of control for individual components integrated within the Communiting Mill shall function as specified in the expected results column in Section 10.3.4.

10.3.4 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Switching on the Power and Utilities to the System				
Switch on the power to Multimill	Machine is ready to start.			
Monitor and Log the readings.	Log the reading of Voltage : 415 $\pm$ 10 %Volts			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.4 Confirmation of Critical Parameter and Full Function Testing

10.4.1 Objective

To confirm that the critical parameter and full function of the Multimill are as defined below:-

- The lubricants used of food grade and they do not come into contact with product or product contact parts

10.4.2 Method

Follow the test methods described in section 10.4.4 for various parameters under test.
Record the observation in 10.4.4 actual results column.
Attach supporting documents, as applicable, in the annexure.

10.4.3 Acceptance Criteria

The critical operational parameters and full function testing on the Multimill has been identified and completed satisfactorily.

10.4.4 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Lubricants are Food Grade & does not come in contact with the Product				
Visual Inspection & test certificates from Vendor	Lubricants are Food Grade & does not come in contact with the Product			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

11.0 CHECKLIST OF ALL TESTS AND CHECKS

This checklist is provided to ensure that all tests or checks required for this protocol have been executed.

Reference No.	Tests or Checks	Executed [Y/N]	Comment
10.1	SOP Verification		
10.2	Start-Up and Shutdown Test		
10.3	Functionality Test		
10.4	Confirmation of Critical Parameter and Full Function Testing		

Comments:

Reviewed by		Date	

12.0 DEVIATION SHEET

Report any deviations from the acceptance criteria or exceptions from protocol instructions in the Record Sheet as described in SOP "Handling Of Deviations" Record the total number of exceptions / deviations reported during the qualification activities of this Protocol. Record the Deviation Number and Title in the Table below. Include all Deviation Record Sheets in the IQ File.

TOTAL NO. OF EXCEPTIONS / DEVIATIONS = _____

Comments:

Reviewed by		Date	

12.1 DEVIATION AND CORRECTIVE ACTION REPORT FORM

This Deviation 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 Deviation Sheet within the protocol.

Deviation Report Number:
PROTOCOL SECTION NO.: **DATE OF TEST:**.....
Description Of Test Result:
IMMEDIATE ACTION TAKEN:
Corrective Action Taken / Planned:
Deviation 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 Deviation? Date of re-test:
Is Deviation Closed (Yes/No):
QA Signature: Date:

13.0 REFERENCES:

The Principle Reference is the following

- Master Validation Plan for Tablets, Capsules, Dry Syrup and dry Powder Injection Manufacturing Facility, VMP/00, Revision 00.
- 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.

The following references are used to give addition guidance

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition / March 2001.
- Code of Federal Regulations (CFR), Title 21, Part 210, *Current Good Manufacturing Practice (cGMP) in Manufacturing, Processing, Packing, or Holding of Drugs*, General. April 1, 1998.
- Code of Federal Regulations (CFR), Title 21, Part 211, *Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals*, April 1, 1998.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.
- European Commission's working party on control of medicines and inspections document, *Validation Master Plan, Design Qualification, Installation & Operational Qualification, Non Sterile Process Validation, Cleaning Validation*, October 1999.
- GAMP Guide, Validation of Automated Systems in Pharmaceutical Manufacture, Version 4.0, December 2001.
- SOP No. "Handling of Deviations".
- SOP No."Change Control Procedure".

14.0 LIST OF ANNEXURES:

Annexure No.	Document Title

15.0 SUMMARY

16.0 POST APPROVALS

The following approvals signify that the OQ is complete and acceptable and that the system is ready for PQ Execution.

PRPARED BY:

Functional area	Name	Signature	Date
Production			

CHECKED BY:

Functional area	Name	Signature	Date
Engineering			
Production			
Quality assurance			

APPROVED BY:

Functional area	Name	Signature	Date
Head Engineering			
Head Manufacturing			