

CHEMPRO PHARAMCH EQUIPMENTS VASAI (E).	DESIGN QUALIFICATIONS PROTOCOL	M/s. ALKEM LABS LTD.
	EQUIPMENT TYPE MULTIMILL	cGMP MODEL

DESIGN QUALIFICATION FOR PROTOCOL

Equipment Name	MULTIMILL
Model No.	PRODUCTION / LAB MODEL
Issue Date:	
Supersedes No.	
Reason for Change	
No. of Protocol Pages	18

Revision control (if any):

Date: Rev. No.....

Description:

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Checked by: - Date. Approved by: - Date

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Protocol Approval Sheet:

	Prepared By	Checked By	Approved By
Signature			
Name			
Date			
Department	Engineering	Engineering	Quality Assurance

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1. OBJECTIVE

The purpose of this design Qualification is to provide documented evidence to demonstrate that all key aspects of the equipments to be built by CHEMPRO PHARMACH EQUIPMENTS. VASAI. Adhere to the M/s. ALKEM LABS. LTD. Requirements and design intentions.

The documented will be finally approved by the clients by the sign out at the foot of each page and a final sign out on the cover sheet.

To design, engineering, supply & installation of the Multimill as per cGMP guidelines and to provide assurance that the equipment is manufactured as per the URS and it complies with the Scope of Supply.

To prove that each operation proceeds as per the design specification and the tolerances prescribed there in the document, are the same at utmost transparency. Validation procedure is set for complete satisfaction of the customer & building confidence of the user about the machine.

2. OVERVIEW

M/s. ALKEM LABS. LTD has placed an order P. O.: to M/s. CPE for the MULTIMILL For the tablet, semi solid raw powder and granulation section.

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1.0 **RESPONSIBILITIES:**

CLIENT:

1. To provide the URS for the equipment.
2. To perform the Factory Acceptance Test (FAT).

MANUFACTURER:

3. To design, manufacture and provide the complete technical details of the equipment pertaining to its design qualification like,
 - Equipment overview,
 - P&ID drawing,
 - Equipment orientation with layout,
 - Specifications of the sub-components/ bought out items, and their make, model & quantity, and backup records/ brochures,
 - Details of Utilities,
 - Identification of components for calibration,
 - Material of construction of all components,
 - Brief process description,
 - Safety features and alarms
 - Pre-installation requirements
2. To facilitate the client for the Factory acceptance test of the machine at their works/ site.
3. To confirm the safe delivery of the equipment to the user site.
4. To ensure that no un-authorized and / or unrecorded design modifications shall take place.
If at any point in time, any change is desired in the mutually agreed design, Change control Procedure shall be followed and documented.
5. To ensure the proper installation and commissioning of the equipment.

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2.0 USER REQUIREMENTS SPECIFICATION (URS):

DESCRIPTION	SPECIFICATIONS
Equipment	Chempro Pharma Equipments - Multimill
Specification	<p>As per the Purchase Order no.</p> <p>Including all Standard accessories with following Scope of Supply:</p> <p>Basic Equipment in cGMP SS 316 construction complete charging & discharge hopper</p> <ul style="list-style-type: none"> ▪ Non flame proof Construction. ▪ TEFC Motor. ▪ Bearing Housing. ▪ SS316 Sieve. ▪ DOL starter. ▪ Castor wheel.
Model	<ul style="list-style-type: none"> ▪ The equipment should be a cGMP model, in terms of surface finish, absence of sharp corners, cleanability, assembling and dismantling of components and control system for its intended use. ▪ Ease of cleanability.
Process	Equipment should be able to perform Crushing of dry granules.
Material of construction	<ul style="list-style-type: none"> ▪ All contact parts are SS316 ▪ Exterior easy to clean, disinfect and non-corrosive. ▪ Material test certificates to be provided.
Calibration	<ul style="list-style-type: none"> ▪ All components that require calibration shall be identified and calibrated. ▪ Calibration certificates shall be obtained from the third party. ▪ Test certificates / calibration charts of sensors & control instruments to be provided.

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DESCRIPTION	SPECIFICATIONS
Qualifications/ Documentation	<ul style="list-style-type: none"> ▪ The manufacturer shall complete and provide the documents pertaining to Design, Installation & Operation Qualification and detail functional specifications including control system with screen design of operating terminal ▪ Information on purchased/bought-out parts. ▪ Operating manual ▪ Trouble shooting tips ▪ Preventive maintenance schedules ▪ Safety precautions
Safety features	<ul style="list-style-type: none"> ▪ Adequate safety features for men and material shall be provided along with the equipment. ▪ Cover up on all rotating parts.
Control system	The equipment shall be controlled through DOL Starter.
Electrical system	<ul style="list-style-type: none"> ▪ The electrical system of the equipment shall be housed as per the cGMP and cGEP standard, with adequate safety ▪ Starter is to be installed on the machine.

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3.0 MACHINE DESCRIPTION:

3.1 Charging Hopper

SS rectangular Charging hopper with flap & inside surface polished to smooth finish with top lid.

Discharge hopper

SS cylindrical bowl which is fixed to top plate through eye bolts.

Beater Assembly

SS beater having 12 nos. with knife and impact edges and 2 scrapper blades. This total assembly of beater is rotated in selected screen.

Agitator Assembly

SS Beater and Scrapper have knife & impact edges which is rotated in selected screen.

Drive Mechanism For Beater

Consist of the following

3 HP 1440 / 2880 RPM TEFC Motor to work on 415 V, 50 Hz, 3 Phase AC supply line, mounted on MS plate cladded with the SS 304 sheet.

The pulley coupled to the motor through belt and pulley arrangement.

Main Body

SS main body is mounted on SS claded base frame. The base frame is mounted on castor wheel.

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4.0 TECHNICAL SPECIFICATIONS:

Output	50 - 200 kg / hr depending on product & reduction
Motor	3 HP / TEFC / 1440 rpm / 440v / 50 hz / 3 ph / AC
Perforated Screen Hole Dia	0.25 - 12 mm as per client requirement.
SS Wire Mesh Sieve	5 - 20 mm
Rotor Assembly Dia	250 mm
Rotor Speed	750 / 1500 /2000 / 3000 rpm
Beaters	12 nos with knife, impact edges & 2 scrapper blades
Screen Dimensions	260 mm dia x 135 height
Charging Height	1445 mm Approx.
Discharging Height	730 mm Approx.
Overall Dimensions	870 x 965 x 1630 (h) mm

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5.0 DETAILS OF UTILITIES

DESCRIPTION	SPECIFICATIONS
1 Electrical	
Phase	3 Phase
Voltage	415V
Frequency	50 Hz

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6.0 IDENTIFICATION OF COMPONENT FOR TEST CERTIFICATE

In the Multimill equipment, following are the components, which needs calibration.

They shall be calibrated during/ before installation of the equipment at the site

Following are the components:

1. MOTOR
2. BEARINGS
3. V- Belt , Pulley Key way, Beater assembly.

7.0 MATERIAL OF CONSTRUCTION

S.NO	COMPONENT DESCRIPTION	MOC
1.	Charging Hopper	SS 316
2.	Beater assembly	SS 316
3.	Sieve holding bracket	SS 316
4.	Sieve	SS 316
5.	Discharge hopper	SS 316
6.	Skid	MS with SS cladding
7.	Motor mounting plate	MS with SS cladding
8.	Covers	SS 304

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8.0 FINISHED DETAILS

S.NO	COMPONENT DESCRIPTION	FINISH
1.	Contact parts	Mirror Finish - Class 4B
2.	Non-contact Parts	Mirror - Class 2B

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9.0 FAT PROCEDURE:

Factory Acceptance Test Procedure shall be as follows:

After the completion of erection work of the machine, client shall be informed to perform the factory acceptance test (FAT).

Client shall perform the FAT at the manufacturer site and record all the data in the prescribed FAT document as per the details given below:

1. Test criteria
2. Design Verification Check list
3. Deficiency & Corrective Action report
4. Pre-installation requirements
5. Final report

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10.0 CHANGE CONTROL PROCEDURE:

Change in the agreed design shall be addressed through the well-defined Change control procedure.

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11.0 DESIGN QUALIFICATION REPORT APPROVAL

17.1 Summary:

17.2 Certification:

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12.0 APPENDIX

12.1 LIST OF ABBREVIATIONS

A	Ampere
AC	Alternative Current
cGMP	Current Good Manufacturing Practice
CS	Carbon Steel
DP	Die Penetration
DQ	Design Qualification
EPDM	Ethyl Propyl Di methylene
GA	General Arrangement
GRIT	Minutes rough granules
HP	Horse Power
IQ	Installation Qualification
MCB	Miniature Circuit Break
MCP	Master Control Panel
MOC	Material Of Construction
PID	Process Instrumentation Diagram
PLC	Programmable Logic Control
PQ	Performance Qualification
QA	Quality Assurance
RPM	Rotation Per Minutes
SS	Stainless Steel
VFD	Variable Frequency Drive

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12.2 REFERENCE DOCUMENTS

1. Manufactures Brochure (s) / Manual (s). (Title and Location).

To be supplied with the Installation qualification documents

1. Instruction & Maintenance manual
2. Calibration certificates
3. Material of construction certificates
5. Test certificates of motors
6. SOP for operation
7. SOP for Preventive Maintenance
8. SOP for Cleaning of the Equipment.

2. Purchase Order Attached (Yes / No). If no, state Location.

Yes – Attached (P.O. No. -----) with DQ Document
Remarks (if any) :

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12.3 ANNEXURE LIST

S.NO.	DESCRIPTION	ANNEXURE NO.
1.	Purchase Order	-----
2.	Equipment GA Drg	-----

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