



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**FAT FOR CONE MILL**

**FACTORY ACCEPTANCE TEST  
FOR  
CONE MILL**



**FAT FOR CONE MILL**

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## FAT FOR CONE MILL

### 1.0 APPROVAL:

This document is prepared by the validation team of ..... for the project 'Hormone OSD Formulations Facility' of ..... under the authority of their QA Head. Hence, this document before being effective shall be approved by the QA Head of .....

PREPARED BY		
NAME	DESIGNATION	SIGNATURE /DATE

CHECKED BY		
NAME	DESIGNATION	SIGNATURE /DATE

APPROVED BY		
NAME	DESIGNATION	SIGNATURE /DATE



## FAT FOR CONE MILL

### 2.0 INTRODUCTION:

- The objective of this protocol is to confirm that the machine Cone Mill manufactured by M/s. ...., at their Works in ..... is in line with the specifications as desired by the customer.
- The objective of this Factory Acceptance Test is to verify that the equipment has been built & engineered according to the design specification and as a result approves the equipment for shipping to ..... Handover will be following completion of successful site acceptance test.

### 3.0 SCOPE:

3.1 The scope of this protocol is limited to the Factory Acceptance Test of Cone Mill.

3.2 Any auxiliary equipment supporting this machine, required along with the machine, for its effective overall performance shall not be tested in this protocol. Any such auxiliary equipment, if present, shall be tested separately.

### 4.0 RESPONSIBILITY

The Qualification group comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this protocol:

Departments	Responsibilities
Quality Assurance	<ul style="list-style-type: none"><li>• Preparation, review, approval and compilation of the FAT Document.</li><li>• Co-ordination with Production and Engineering to carryout activity.</li></ul>
Production	<ul style="list-style-type: none"><li>• Review of FAT Document.</li></ul>
Engineering	<ul style="list-style-type: none"><li>• Review of FAT Document.</li><li>• To co-ordinate and support FAT Activity.</li></ul>

### 5.0



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**6.0 VERIFICATION OF TECHNICAL SPECIFICATIONS OF SUB-COMPONENTS & BOUGHT OUT ITEMS:**

S.No.	Design/Component	Description	Observation	Remark
1	Model	PCOM-250		
2	Machine	Cone Mill		
3	Features	In line size reduction with vacuum transfer system.		
4	Product contact parts	S.S.316		
5	Non Product contact parts	S.S.304		
6	Product Contact parts Finish	Ra 0.5 Mirror		
7	Non Product Contact parts Finish	Ra 0.8 Matt		
8	Output Kg/Hour	100 to 500 Kg/Hour		
9	Screen Span	251 mm		
10	Rotor	Cone Type		
11	Rotor Speed	100 to 1440 RPM by VFD.		
12	Fitted sieve size	2.5 mm hole size		
13	Electric Power	5 Hp / 3.75 Kw		
14	Rotor Drive	Direct with motor.		
15	Electric controls panel	Electric Controls panel with push button.		
		On-off push button Function, RPM Set & Actual		
		Amp Meter - Actual. Main Isolate switch.		
		Emergency Stop Switch. MCB, Contactor, Relay, Controls relay & SMPS.		
16	Documents	Machine Instruction manual with assembly drawings, parts list and electric wiring diagram.		
		Validation documents for		



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S.No.	Design/Component	Description	Observation	Remark
		DQ,FAT,IQ,SAT,OQ Test certificate & MOC Certificate.		
17.	<b>Require Utilities</b>			
	Electric Power	3.75kw/3 phase/415V/50Hz.		
	Steam	Nil		
	Compressed Air	Nil		
	D.M. water	Nil.		
	Hot water	For washing required.		
	Plain water	For washing required.		
	D.M. water	For washing required.		

**7.0 VERIFICATION OF MATERIAL OF CONSTRUCTION CERTIFICATES**

S.No.	Component	MOC	Observation	Remarks
1.	Contact part	SS 316		
2.	Sieve	SS 316		
3.	Non contact part	SS 304		
4.	Main Body	SS 304		
5.	Rubber Seal			

**8.0 VERIFICATION OF SAFETY FEATURES**

S.No.	Features	Observation	Remarks
1	Safety interlocks limit switch for charging hopper & discharge hopper.		
2	Overload relay controls.		
3	Emergency stop.		



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**9.0 VERIFICATION OF TEST/CALIBRATION CERTIFICATES**

S.No.	Component	Status	Observation	Remarks
1.	Material of construction	Test Certificate		
2.	Main Drive Motor	Test Certificate		
3.	Electrical drawing	Should be available		
4.	GA Drawing	Should be available		
5.	P & ID Drawing	Should be available		

**10.0 VERIFICATION OF SURFACE FINISH**

S.No.	Component	Surface Finish- Mirror/ Matt	Observation	Remarks
1.	Product contact part	Mirror		
2.	Non product contact part	Matt		







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**12.0 SUGGESTIONS / MODIFICATIONS**

S.No.	SUGGESTION FROM ..... (IF ANY)	MANUFACTURER'S ACCEPTANCE
1.		
2.		
3.		
4.		
5.		

**13.0 ABBREVIATIONS**

Acronym	Definition
OSD	Oral solid dosage form
QA	Quality Assurance
FAT	Factory acceptance test
A.C.	Alternating current
HP	Horse power
Kw	Kilo-watt
VFD	Variable frequency drive
MCB	Miniature circuit breaker
PO	Purchase order
EC	European commission
V	Volt
Hz	Hertz
NA	Not applicable
EU	European union
cGMP	Current Good Manufacturing Practice
GMP	Good Manufacturing Practices



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**14.0 POST APPROVAL**

Name	Designation	Department	Signature

.....

Name	Designation	Department	Signature