



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

FACTORY ACCEPTANCE TEST FOR CONE MILL

Department: Quality Assurance

FAT No.:

Title: Factory Acceptance Test for Cone Mill

Effective Date:

Supersedes: Nil

Review Date:

**FACTORY ACCEPTANCE TEST
FOR
CONE MILL**

Vendor:

	Title	Name	Signature	Date
Prepared by	Project Engineer			
Reviewed by	Quality Engineer			
Approved By	Quality Manager			

Pharmadevils Approvals:

Title	Name	Signature	Date
Quality Assurance			
Project Engineer			
Project Consultant			



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1 INTRODUCTION:

The objective of this Factory Acceptance Test is to verify that the equipment has been built and engineered according to the design specification and as a result approves the equipment for Shipping to Pharmadevils. Handover will be following completion of successful site acceptance test.

This document will be completed as follows:

1. All people who enter data into this report will complete the section of this FAT titled 'FAT Personnel'.
See Appendices. A, B, C, D, E, F.
2. Any corrections in handwriting will be made by deleting with a single pen stroke; the correction will be initialed and dated.
3. Entries shall be made in this document using a ballpoint pen or suitable indelible ink in Blue only.
4. Compliance will be indicated by a written Pass/Fail in the relevant boxes provided. 'Ticks' and 'crosses' must not be used.
5. Correction fluid is not allowed.
6. Each section will be signed and dated by the tester/s when it is complete.
7. Any non-compliance identified during the execution of the test protocols must be documented in a Deviation report. These report sheets must be attached to the appendix of this protocol. The report will describe the deviation in detail and, whenever possible, identifying the cause.



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2 OVERVIEW:

..... has received an order for the material procurement, and manufacture and supply of 1 No. of CONE MILL from vide their purchase order Dated

3. DOCUMENT VERIFICATION:

DOCUMENT VERIFICATION

Objective	Ensure that all relevant design documentation is in place and referenced.
Method	Log the document title, reference number, approval date and revision number. Any discrepancies to be noted on the review form and on the Deviation Report.
Acceptance Criteria	All columns in the table should be completed. All documents should be identified, approved and referenced.

Document Expected	Reference Number	Rev	Approval Date	Available Yes/No
Purchase Order				
G A Drawing				
URS				
FDS				
DQ				
Electrical Wiring Diagram				
Material chart				
Operating Manual				
Manual for bought out components:				

Comments

	Signed	Date
Executed By:		
Reviewed By:		



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MAJOR COMPONENT VERIFICATION

Objective To verify that the Major Components are installed in accordance with the approved GA drawings.

Method Take a copy of the approved GA drawing no. Highlight in yellow the components present on the machine in the drawing then fill the table below. Fill in the drawing number when verified. Attach the highlighted drawing with this document. Any discrepancies to be noted on the review form and on the Deviation Report.

Acceptance Criteria There should not be any variance with approved GA Drawing

S.No.	PART	MODEL / SIZE /MOC	MAKE	Pass/Fail
1.	Bearing housing	SS 304	Vendor	
2.	Charging Hopper	SS 316	Vendor	
3.	Stand	SS 304	Vendor	
4.	Impeller	SS 316	Vendor	
5.	Shaft	SS 316	Vendor	
6.	Motor	HP-3,RPM-1440, NFLP	Crompton	
7.	Control Panel cum Operating	SS	Vendor	
8.	Discharge Hopper	SS 316	Vendor	
9.	Sieve	SS316,8MM Hole size	Vendor	
10.	Operating panel			

Comments

Signed

Date

Executed By:

Reviewed By:



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EQUIPMENT MOC VERIFICATION

Objective	To verify that the material of construction of the machine is as per Material chart.
------------------	--

Method	Verify the material chart and the test certificates available with respect to acceptable standards. Attach the copy of the material chart along with this document. Use a yellow highlighter pen to mark the components verified. Note down any discrepancy in the discrepancy report in this document.
---------------	---

Acceptance Criteria	The MOC and test certificates thereof must comply with the requirement of approved documents.
----------------------------	---

Drawing no.
--------------------	-------

Comments:

	Signed	Date
Executed By:		
Reviewed By:		



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EQUIPMENT DIMENSION VERIFICATION

Objective:	To verify that the equipment manufactured is in accordance with approved drawing.
Procedure:	Refer to the approved drawing no. and compare with the actual dimensions on the equipment. Recheck whether the drawing clearly specifies the manufacturing standards adopted. With a red pen clearly strike out any incorrect dimension and insert the correct dimension. Correct the drawing with the proper dimensions and name the drawing "AS BUILT". Attach the marked drawing with this Document
Acceptance Criteria	The measured dimensions should be within the acceptable limits.

Drawing no-
.....

Comments:

	Signed	Date
Executed By:		
Reviewed By:		



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CRITICAL DIMENSION VERIFICATION

Objective:	To verify that the critical dimensions are met as given in the approved GA drawing.		
Procedure:	Refer the approved drawing and compare with the actual dimensions on the equipment. Recheck whether the drawing clearly specifies the manufacturing standards adopted. With a red pen clearly strike out any incorrect dimension and insert the correct dimension. Document it in the deviation if dimensions are out of acceptable limits.		
Acceptance Criteria	The measured dimensions should be within the acceptable limits.		
	All Dimensions under 1000mm +/- 3mm		
	All Dimensions over 1000mm +/- 5mm		
	Critical hole centres +/- 2mm.		

Drawing No.:

Critical Dimension	As mentioned in GA Drawing no.	Actual	Pass/Fail
Charging HT.	1855 mm		
Discharge HT.	925 mm		

Comments:

	Signed	Date
Executed By:		
Reviewed By:		



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EQUIPMENT FINISH VERIFICATION

Objective:	To ensure that the equipment finish is as per the approved drawing.
Procedure:	<p>Stainless Steel Internal finish:</p> <ul style="list-style-type: none">▪ There should be a no exposed threads.▪ There should be no crevices or sharp corners, weld splatters.▪ Edges should be smooth and rounded off.▪ Using an RA meter or comparative plate check the external finish▪ No scratches should be present on the surface.▪ Mild. Steel. Parts should be properly descaled, degreased, and painted. <p>Other equipment/components should be properly cleaned, debarred, and should have no sharp edges. Any discrepancies to be noted on the review form and on the Deviation Report.</p>
Acceptance Criteria	The finish should be as per the approved drawing and as above

Part	Finish SS Surface	Finish as specified in the approved documents	Pass/Fail
Charging Hopper	Internal	Ra-0.4 (240 Grit Mirror)	
	External	Ra-0.6 (180 Grit Mirror)	
Discharge Hopper	Internal	Ra-0.4 (240 Grit Mirror)	
	External	Ra-0.6 (180 Grit Mirror)	
Mixing Chamber	Internal	Ra-0.4 (240 Grit Mirror)	
	External	Ra-0.6 (180 Grit Mirror)	

Comments:

Signed	Signed	Date
Executed By:		
Reviewed By:		



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EQUIPMENT NAME PLATE VERIFICATION

Objective:

To ensure that the Nameplate is provided on the machine and is easily visible. It should clearly mention the name, reference no. of the machine and the date of manufacture.

Procedure:

Visually inspect the machine for the Nameplate and check whether it contains the date, reference no. and date of manufacture. Mark /highlight the location on the drawing. Any discrepancies to be noted on the review form and on the Deviation Report.

Acceptance Criteria

The Nameplate has all the above data inscribed on it.

DESCRIPTIONS	VERIFIED (YES/NO)
Name Plate Location is Acceptable and marked on the drawing?	

Model:	GMP	Capacity:	25-300 kg/hr.	Pass/Fail
Type:	CONE MILL	Date Of Mfg.:		
MOC:	SS316	Inspection By:	CLIENT	
Sr. No:				

Comments:

Signed	Date
Executed By:	
Reviewed By:	



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CONTROL PANEL BUILD QUALITY

Objective:	To ensure that the electrical equipments are assembled as per electrical GA drawings.
Procedure:	Check orientations, drawings, and placement of switchgears as per GA. Highlight the components on the GA, so verified. Any discrepancies to be noted on the review form and on the Deviation Report.
Acceptance Criteria	All the equipments are assembled as per GA.

Description	Verified Yes/No
Electrical Equipments orientations are as per GA Drawing	
Electrical Wiring Diagram Attached?	
Panel Build Quality Acceptable?	

Comments:

	Signed	Date
Executed By:		
Reviewed By:		



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ELECTRICAL WIRING DIAGRAM

Objective:	To compare the electrical components in the panel and the wiring identification with the electrical drawings.
Procedure:	<p>The tester will compare the installed components with those specified on the drawings and check the wiring identification is as shown on the drawings and will mark with a 'highlighter' pen each of the details on the drawing which are verified. A minimum of 20% of the components fitted will be checked and highlighted. Any correction to the drawing will be written on the drawing by the relevant item in RED ink.</p> <p>When the tester has completed the check, they will date and sign the marked-up print and write the words: - 'FACTORY ACCEPTANCE TEST ELECTRICAL COMPONENTS CHECK'</p> <p>The tester will attach the Marked-Up print to this report as an appendix given below. All attachments to this protocol to be marked up with this protocol number including the number of pages and the appendix to which it is attached.</p> <p>Any items on the drawings in non-compliance will be detailed in a deviation report.</p>
Acceptance Criteria	The connections are as per the wiring diagrams.

Electrical Drawing No.	Rev. No.	Pass/Fail

Comments:

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ELECTRICAL COMPONENT/WIRING TAG VERIFICATION

Objective

Confirm that all the electrical Components/Wires are as per given Tag in the drawings no. _____.

Method

Verify that the tags on the Components and wires are as per the wiring diagrams. Fill in the table below. Any discrepancies to be noted on the review form and on the Deviation Report.

Acceptance Criteria

The tag Numbers should tally.

S.No.	Description Of components	Type / Specification	Qty.	Make	Actual	Verified Yes/No

Comments:

	Signed	Date
Executed By:		
Reviewed By:		



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WIRING TUG TEST

Objective	Confirm that all the wires are connected to the electrical components tightly.
Method	Lightly pull all the wires connected to the electrical components one by one testing any loose connections. Redo the connection if any is found loose. Any discrepancies to be noted on the review form and on the Deviation Report.
Acceptance Criteria	Ensure all wires connected tightly to the electrical components.

Comments:

	Signed	Date
Executed By:		
Reviewed By:		



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TEST INSTRUMENTS

Objective	To identify the equipment and instruments used for testing during the Factory Acceptance Test phase and to verify that they were calibrated.
Method	List all test or reference instruments used during the Factory Acceptance Test of the system. Include the description, serial number, manufacturer, and calibration for each item, as applicable. Verify that all such instruments are calibrated and attach the relevant calibration certificates to this protocol. Document the results in the table below. Any discrepancies to be noted on the review form and on the Deviation Report.
Acceptance Criteria	All instruments used to qualify the system during Factory Acceptance Test shall be listed along with their description, serial number, Certificate number, calibration dates, as applicable. For each instrument, a copy of the calibration certification is to be included with this protocol or its location referenced.

Instrument	Serial Number	Certificate Number	Available Yes / No
RA Meter			
Thermometer			
Tachometer			

Comments:

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LOAD TRIAL VERIFICATION

Objective	To verify the functionality of the Cone Mill
Method	Put the coarse powder in the charging hopper.
Acceptance Criteria	Coarse powder milled properly. All joints are found to be sealed, with no powder leakage, at 1 mm partial size.

Operations	Speed (rpm)	Sound Level	Current drawn (Amp) R, Y, B	Temp
Motor Performance	1440	<80db (will be performed at SAT)	4.5 AMP	<80 ^{0c}

Comments:

	Signed	Date
Executed By:		
Reviewed By:		



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Post approval

Completion of the FAT, including satisfactory resolution of all discrepancies noted during execution, will be documented below, signed by the person with overall review responsibility for the protocol, and by the client's authorized signatories who approved the protocol.

Agreed Criteria			Agreement YES / NO
1. Approval for shipment			
2. Machine is approved for shipment following correction of all deviations noted during FAT			
3. Machine is not approved & will require repeat FAT following correction of all deviations.			
Vendor			
Reviewed By	Print Name	Signature	

Client			
	Print Name	Signature	Date
Consultant			
Engineering			
Quality Assurance			



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CLEANLINESS AND APPEARANCE

Objective	Equipment and parts thereof properly cleaned after the Factory acceptance tests
Method	Physically examine the internal wetted part of equipment. Ensure there is no material retention, all surfaces are properly washed and fit for client use fill out the table below. External Surface: All surfaces should be cleaned for stains or marks if any. Visually inspect the cleaning after it is complete. Any discrepancies to be noted on the review form and on the Deviation Report.
Acceptance Criteria	Machine should be thoroughly cleaned

Part		Part Cleaned Yes/No
Charging Hopper	External	
Charging Hopper	Internal	
Discharge Hopper	External	
Discharge Hopper	Internal	
Milling Chamber	External	
Milling Chamber	Internal	
Operating cum Control panel	External	
Impeller	External	

Comments:

	Signed	Date
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Reviewed By:		



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POST FAT DOCUMENT

Objective	The machine has been dismantled and packed in accordance with PO and site conditions
Method	Machine should be dismantled, marked and matched to facilitate ease of Installation. Individual Sub-assemblies/components so dismantled should be wrapped in plastic and packed in accordance with the Shipment protocol. In case of over seas assignments painted parts should be greased and labeled” DE-GREASE BEFORE USE”. Sub-assemblies/components should be properly secured to packing to prevent transit damage A detailed packing list will be filled as per format and signed out.
Acceptance Criteria	Packing list should be complete and no. of components must tally with list. Packing sizes should be in accordance with commercial documentation.

Comments:

	Signed	Date
Executed By:		
Reviewed By:		



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APPENDIX B - CALIBRATION CERTIFICATES REGISTER:

Number	Description	Attached Yes/No

Comments

Tested By:		Approved By
Date		Date



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APPENDIX C: DEVIATION REPORTS PROCEDURE:

During FAT testing, a Deviation Report must be raised when there is a failure to meet acceptance criteria.

The aim is to:

- Clearly describe the deviation.
- To document and approve the evaluation of the impact of the deviation.
- To document and approve the corrective action required to resolve it.
- To document the closing out of the deviation with the appropriate approvals.

Procedure:

- a. If a test step fails to meet test acceptance criteria/method then a Deviation Report must be raised. See Appendix.
- b. All Deviation Reports must be logged by completing the Deviation Report Register. See Appendix
- c. Each Deviation Report must reference the following identification numbers:
 - a. Protocol document reference number.
 - b. The applicable test reference number (XX) as defined in the protocol.
 - c. A unique deviation reference number, which comprises the specific test number and a sequential deviation number (YY) for that test in the format XX/YY. Subsequent deviations on the same
- d. The person raising the deviation must clearly describe the exact nature of the deviation (why acceptance criteria/method has not been met) using the 'details of deviation noted' box provided.
- e. The deviation must be fully evaluated and the necessary corrective action formulated and must be pre-approved by Vendor & the Client. The findings of this evaluation together with details of corrective action required to resolve the deviation should be clearly documented by completing the 'evaluation of deviation/corrective actions to be taken' box.
- f. Once the proposed corrective action has been pre-approved, the tester will execute the corrective work and verify implementation of corrective action by completing the 'Results of Corrective Action' box. The tester will then sign and date the Deviation report.
- g. The completed Deviation Report will require approval by the appropriate personnel on the Deviation Report.

Completed Deviation Reports must be attached to the Appendix of this FAT



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APPENDIX E - DEVIATION REPORT SHEET

Deviation No:		Test Reference:	
----------------------	--	------------------------	--

Details of Deviation Noted:

Completed By:

Date:

Evaluation of Deviation / Corrective Actions To Be Taken:

Completed By:

Date:

PRE-APPROVALS - EVALUATION / CORRECTIVE ACTIONS

The following signatures pre-approve the content of the evaluation and the necessary corrective actions to be taken.

Function	Pre-Approval Required (Yes / No)	Name (Print)	Signature	Date
Vendor				
Client				

Results of Corrective Action:

Completed By:

Date:



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APPROVALS - RESULTS OF CORRECTIVE ACTIONS/ DEVIATION CLOSE OUT

The following signatures approve the results corrective actions taken and the closure of the deviation.

Approvals	Name (Print)	Signature	Date
Vendor			
Client			

