



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

FACTORY ACCEPTANCE TEST FOR FLUID BED DRYER

Department: Quality Assurance

FAT No.:

Title: Factory Acceptance Test for FBD

Effective Date:

Supersedes: Nil

Review Date:

**FACTORY ACCEPTANCE TEST
FOR
FLUID BED DRYER**



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APPROVAL

INITIATED BY:

| DESIGNATION | NAME | SIGNATURE | DATE |
|--|------|-----------|------|
| OFFICER/EXECUTIVE (QUALITY ASSURANCE) | | | |

REVIEWED BY:

| DESIGNATION | NAME | SIGNATURE | DATE |
|--------------------------------|------|-----------|------|
| HEAD (PRODUCTION) | | | |
| HEAD (ENGINEERING) | | | |

APPROVED BY:

| DESIGNATION | NAME | SIGNATURE | DATE |
|-------------------------------------|------|-----------|------|
| HEAD (QUALITY ASSURANCE) | | | |

INTRODUCTION:

- The objective of this protocol is to confirm that the machine Fluid Bed Dryer manufactured by M/s., at their Works in is in line with the specifications as desired by the customer.



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- 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.

SCOPE

- The scope of this protocol is limited to the Factory Acceptance Test of Fluid Bed Dryer.
- 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.

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



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VERIFICATION OF TECHNICAL SPECIFICATIONS OF SUB-COMPONENTS & BOUGHT OUT ITEMS.

| S.No. | Parameter | Specifications | Observation | Remarks |
|-------|---------------------------------|--|-------------|---------|
| 1. | Working Volume | 525/750 liters | | |
| 2. | Working capacity | 250 Kg | | |
| 3. | Blower | | | |
| | Electric motor | Make: 30 HP/ 22.75Kw | | |
| | Air flow of blower | Make: 4800 cfm | | |
| | Static pressure | 750mm of water | | |
| 4. | Utilities | | | |
| | Steam pressure | 3-4 kg/cm ² | | |
| | Electric heater | 30Kw | | |
| | Compressed air consumption | 20cfm | | |
| | Compressed air pressure | 6 bar | | |
| 5. | Range | | | |
| | Drying temperature | 35 to 95°C | | |
| 6. | Material of construction | | | |
| | Product contact part | SS 316 | | |
| | Non Product contact part | SS 304 | | |
| | Product contact part finish | Ra 0.5 mirror | | |
| | Non Product contact part finish | Ra 0.8 matt | | |
| 7. | Electrical Control Panel | | | |
| | | PLC control with screen panel | | |
| | | 3 level password | | |
| | | Product wise parameter – recipe management | | |
| | | On/off function | | |
| | | Auto material loading from RMG program screen | | |
| | | Complete process cycle controls on time by PLC | | |
| | | Auto pneumatic sealing of bowl & filter bag | | |
| | | Auto filter bag shaking on time basis | | |
| | | Auto inlet & exhaust | | |



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| S.No. | Parameter | Specifications | Observation | Remarks |
|-------|---|--|-------------|---------|
| | | damper closed/open | | |
| | | On/off for electric heater | | |
| | | Inlet air temperature PID control set/ actual | | |
| | | Exhaust air & product bed temperature display (actual) | | |
| | | Exhaust blower RPM set with VFD | | |
| | | Differential pressure HEPA/ product sieve/ filter bag | | |
| | | Solid flow detection sensor | | |
| | | Main isolate switch | | |
| | | Emergency stop switch | | |
| | | MCB, Contactor relay controls relay & SMPS | | |
| 8. | Exhaust Blower Motor | Make: HP: RPM: A:..... Hz:..... | | |
| 9. | Pneumatic Cylinder for filter bag shaking | MAKE: | | |
| 10. | Filter Bag | MAKE: MOC: | | |
| 11. | Temperature Sensor | MAKE: MOC: Model: | | |
| 12. | Inlet air Temperature Controller | Make: MOC: Model: | | |
| 13. | Bed Temperature | Make: MOC: Model: | | |
| 14. | AMPERE Meter | Make: Model: | | |
| 15. | MCB | Make: | | |



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| S.No. | Parameter | Specifications | Observation | Remarks |
|-------|------------------|---|-------------|---------|
| | | Model: | | |
| 16. | Contact | Make: Model: | | |
| 17. | Control Relay | Make: | | |
| 18. | Pneumatic Valve | Make: Model: | | |
| 19. | Pneumatic Valve | Make: Model: | | |
| 20. | FRL | Make: Model: | | |
| 21. | Inlet Pre Filter | Make: MOC:HDPE Model: Efficiency: 90% down to 10 μ | | |
| 22. | Final Filter | Make: MOC:HDPE + Al. mesh Model: Efficiency: 90% down to 5 μ | | |
| 23. | HEPA Filter | Make: MOC: sub Micronics glass fiber Model: Efficiency:99.97% down to 0.3 micron | | |
| 24. | Filter Bag | Make: MOC: Model: Efficiency: | | |



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VERIFICATION OF MATERIAL OF CONSTRUCTION CERTIFICATES

| S.No. | Component | MOC | Observation | Remarks |
|-------|-----------------------------|---------|-------------|---------|
| 1. | Product Container | SS 316 | | |
| 2. | Sieve for product container | SS 316 | | |
| 3. | Bottom Chamber | SS 316 | | |
| 4. | Inlet Air unit | S.S.304 | | |
| 5. | Main Body | SS 304 | | |
| 6. | Blower casing | | | |
| 7. | Blower fan | | | |
| 8. | Rubber Seal | | | |
| 9. | Filter Bag | | | |



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VERIFICATION OF SAFETY FEATURES

| S.No. | Features | Observation | Remarks |
|-------|--|-------------|---------|
| 1. | Safety interlock with bowl position | | |
| 2. | Dampers position sensor | | |
| 3. | Inter lock of product container & filter bag sealing | | |
| 4. | Differential pressure interlock for HEPA, Filter bag & product sieve | | |
| 5. | Solid flow detection in exhaust air with interlock for shutoff | | |
| 6. | Compressed air pressure interlock | | |
| 7. | Auto stop when sets time achieved | | |
| 8. | Emergency stop | | |



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VERIFICATION OF TEST/CALIBRATION CERTIFICATES

| S.No. | Component | Status | Observation | Remarks |
|-------|------------------------------------|---------------------|-------------|---------|
| 1. | Main Drive Motor | Test Certificate | | |
| 2. | Inlet Air temperature controller | Test Certificate | | |
| 3. | Exhaust Air temperature controller | Test Certificate | | |
| 4. | Process Timer | Test Certificate | | |
| 5. | Cyclic Timer | Test Certificate | | |
| 6. | Electrical drawing | Should be available | | |
| 7. | GA Drawing | Should be available | | |
| 8. | P & ID Drawing | Should be available | | |

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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SUGGESTIONS / MODIFICATIONS

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

ABBREVIATIONS

| Acronym | Definition |
|---------|--|
| OSD | Oral Solid Dosage |
| QA | Quality Assurance |
| FAT | Factory acceptance test |
| FBD | Fluidized bed dryer |
| MMI | Man machine interface |
| PLC | Programmable logical control |
| AC | Alternating current |
| HP | Horse power |
| Kw | Kilo-watt |
| CFM | Cubic feet per minute |
| VFD | Variable frequency drive |
| MCB | Miniature circuit breaker |
| PO | Purchase order |
| EC | European commission |
| V | Volt |
| Hz | Hertz |
| NA | Not applicable |
| HEPA | High efficiency air particulate filter |
| EU | European union |
| cGMP | Current Good Manufacturing Practice |
| GMP | Good Manufacturing Practices |



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POST APPROVAL

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|------|-------------|------------|-----------|
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