



PHARMA DEVILS

PRODUCTION DEPARTMENT

USER REQUIREMENT SPECIFICATION

NAME OF ITEM: De-Dusting Unit

PROTOCOL No.....

FUNCTIONAL AREA: Production

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**USER REQUIREMENT
SPECIFICATION
(SECTION: FORMULATION)**

Equipment Name

De-Dusting unit

User Department

Exhibit Batch area



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(A) PROCESS/PRODUCT REQUIREMENTS:

1.0 Name/Description of the equipment:

De-Duster is required to attach at the outlet of compression machines to remove the dust and burrs of tablets online during compression operation.

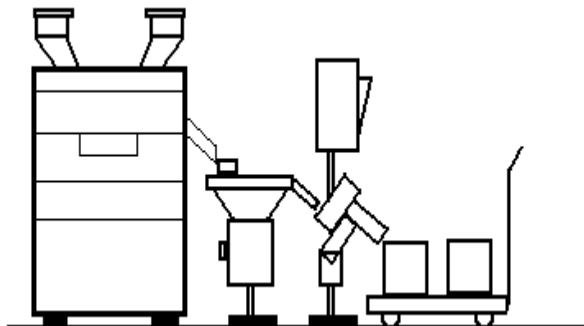
2.0 Purpose of the equipment:

To remove the dust and burrs of all shapes of tablets online during compression operation on all type of the tablet compression machines.

3.0 Number of equipments required:

1 Nos.

4.0 Tentative process schematic flow diagram:



Compression machine

De-dusting unit

Metal detector

Collection bin

5.0 Product dosage type:

Solid oral dosage form (Uncoated Tablets)

6.0 Suppliers name:

M/s.

7.0 Requirements for any power failure backup's or other utilities:

NA

8.0 Any specific requirements:

- 1 Vertical from bottom to top
- 2 Height of the equipment should be adjustable as per outlet chute of the compression machine as well as inlet of the metal detector unit.



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- 3 The equipment should be provided with castor wheels (With lock system) for ease of shifting and positioning.
- 4 Low noise operation
- 5 No starting and stopping jerk.

(B) OPERATIONAL REQUIREMENTS

1.0 Production stage:

De-dusting of tablets after the Compression.

2.0 Material inputs into the equipment:

Compressed tablets from the compression machine will enter through inlet chute of De-dusting Unit.

3.0 Desired out come from the equipment:

Tablets with no adhered dust & burrs should come out. The dust & burrs should be removed with the help of DEX pipe supplied to the De-dusting Unit.

4.0 Charge size/Lot size

NA

5.0 Method for loading material into the equipment:

Compressed tablets will come out from outlet chute of Compression machine and enter directly in inlet chute of De-dusting Unit.

6.0 Method for unloading material from the equipment:

The compressed tablets from De-dusting Unit directly enter into the inlet chute of metal detector. After metal detection, the tablets are to be collected into collecting bin (i.e. ruby containers).

7.0 Expected running time per day:

8.0 hours per shift (normally 3 shift working is assumed).

8.0 Method of cleaning:

- Vacuum system for adhered powder.
- Water jet to be forced manually and then wiping with dry lint free cloth.

9.0 Recommended solvent for cleaning:

Purified water.



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10.0 Utilities required:

- Electric connections as per the equipment requirement.
- DEX system

11.0 Instrumentation

12.0 Process Control requirement

NA

13.0 Change over Part requirement

NA

14.0 Available size of the Room for installation

Exhibit Batch Area

Room No. FN 58 (3.8 * 5.6 Sq. Meter)

15.0 Online attachment with other equipment

- Indicator lamp should be there to show the status of operation.
- Compressed air connection should be provided at top lid.

16.0 Any other specific requirements:

- Equipment should be designed in such a way that it can be transported from one place to another using provided wheel for cleaning or maintenance work.
- Indicator lamp should be there to show the status of operation.
- Compressed air connection should be provided at top lid.

(C) GMP REQUIREMENTS

Material of construction specification:

- Product contact parts : SS316.
- Non contact parts to product : SS304.
- Castor wheel : PU

Working area environment requirement:

- Equipment is to be placed in production (“O”) area. Temp. 25°C & RH is 20%
- Equipment is to be placed in such a way that most of the maintenance work of electrical problem is attended through technical (“F”) area and mechanical work to be attended in the cubicle itself.



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- **GMP requirements**
- **Filter requirement on utility lines or for vent purpose**
NA.

(D) DOCUMENTATION REQUIREMENTS:

- Manual (Operational & maintenance)
- Electrical wiring diagram
- Material of Construction (MOC) Certificate
- Bought-out item certificate
- P & I diagram
- Variable frequency drive internal/external electrical diagram.
- DQ, IQ and OQ Documents.

(E) SAFETY REQUIREMENTS

- (1) **Information related to safety**
NA
- (2) **Process Control Alarms**
Buzzer to inform end of process.
- (3) **Safety Interlocks**
NA.
- (4) **Password protection (In case of PLC systems)**
NA.
- (5) **Any other specific requirement**
NA.



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(H) USER REQUIREMENT SPECIFICATION APPROVAL:

PREPARED BY

Name & Designation	Sign & Date

CHECKED BY

Name & Designation	Sign & Date

APPROVED BY

Name & Designation	Sign & Date