

# PHARMA DEVILS

PRODUCTION DEPARTMENT

| STANDARD OPERATING PROCEDURE   |                     |  |  |  |  |
|--|---------------------|--|--|--|--|
| Department: Production   | SOP No.:            |  |  |  |  |
| <b>Title:</b> Inventory and storage of FBD/FBP Finger Bag / RMG filter Bag / Air Jet Micronizer Filter Bag / Air jet micronizer filter bag | Effective Date:     |  |  |  |  |
| Supersedes: Nil  | <b>Review Date:</b> |  |  |  |  |
| Issue Date:  | Page No.:           |  |  |  |  |

#### Vernacular SOP No.:

### 1.0 OBJECTIVE:

1.1 To lay down a procedure for Inventory and Storage of FBD/FBP Finger Bag/RMG Filter Bag/Air Jet Micronizer Filter Bag.

#### 2.0 SCOPE:

2.1 This procedure is applicable to Inventory and Storage of FBD/FBP Finger Bag/RMG Filter Bag/Air Jet Micronizer Filter Bag in Production Department.

#### 3.0 RESPONSIBILITY:

- 3.1 Technical Associate: Cleaning and Operation of equipment.
- 3.2 Officer and Executive: Execution of cleaning and operation of equipment
- 3.3 Head Production: SOP compliance
- 3.4 IPQA Person: Line Clearance

## **4.0 DEFINITION(S):**

4.1 NA

# 5.0 PROCEDURE:

#### 5.1 For Inventory

- 5.1.1 On intimation of receipt from stores, collect all the FBD/FBP finger bag / RMG Filter Bag/ Air Jet Micronizer filter bag.
- 5.1.2 Check the integrity of individual FBD/FBP finger bag / RMG Filter Bag/ Air Jet Micronizer filter bag and record the observations in Annexure-I, Annexure-II, Annexure III and Annexure-IV.
- 5.1.3 Remark 'OK' for pass FBD/FBP finger bag / RMG Filter Bag/ Air Jet Micronizer filter bag and 'Not OK' for FBD/FBP finger bag / RMG Filter Bag/ Air Jet Micronizer filter bag which fails the integrity test. Return back the defective FBD/FBP finger bag / RMG Filter Bag/ Air Jet Micronizer filter bag to stores.
- 5.1.4 Allot a code no. as per SOP to the pass FBD/FBP finger bag / RMG Filter Bag/ Air Jet Micronizer filter bag and transfer the respective storage area.
- 5.1.5 Record the observations in Annexure-I, II, III and IV.
- 5.1.6 Clean the FBD/FBP finger bag / RMG Filter Bag/ Air Jet Micronizer filter bag as per SOP.

### 5.2 Storage of FBD/FBP finger bag and RMG filter bag



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- 5.2.1 Place completely dried FBD/FBP finger bag and RMG filter bag in individual polythene bags and affix dully filled and signed 'CLEANED' label as per SOP.
- 5.2.2 Ensure that the product specific storage cabinet is empty, clean and dry.
- 5.2.3 Place the packed and labeled FBD/FBP finger bag and RMG filter bag in the product specific storage cabinet.
- 5.2.4 While Issuance and receiving back the FBD/FBP finger bag / RMG filter bag for corresponding product, record the observations in Annexure-I, Annexure-II & annexure III.

## 5.3 Storage of Air Jet Micronizer filter bag

- 5.3.1 Place completely dried Air Jet Micronizer filter bag in individual polythene bags and affix dully filled and signed 'CLEANED' label as per SOP.
- 5.3.2 Ensure that the product specific storage cabinet is empty, clean and dry.
- 5.3.3 Place the product specific six cleaned filter bag in one polythene bag and affix dully filled and signed 'CLEANED' label as per SOP.
- 5.3.4 Place the packed and labeled Air Jet Micronizer filter bag in the product specific storage cabinet.
- 5.3.5 While Issuance and receiving back the Air Jet Micronizer filter bag for corresponding product, record the observations in Annexure-IV.

#### 5.4 Precaution

- 5.4.1 Do not store FBD/FBP finger bag / RMG filter bag/ Air Jet Micronizer filter bag in wet condition.
- 5.4.2 Store FBD/FBP finger bag / RMG filter bag/ Air Jet Micronizer filter bag in product specific clean and dry cabinet only.

#### 6.0 **ABBREVIATION(S):**

| 6.1 | FBD | : | Fluidized Bed Dryer. |
|-----|-----|---|----------------------|
|-----|-----|---|----------------------|

6.2 FBP : Fluidized Bed Processor.

6.3 SOP : Standard Operating Procedure

Stainless Steel

RMG : Rapid Mixer Granulator

SS

7.0

7.1 SOP: Coding of accessories

**RERERENCE(S):** 

- 7.2 SOP: Cleaning and utilization of FBD/FBP finger bag and RMG filter bag/Micronizer filter bag.
- 7.3 SOP: Status Labeling



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# 8.0 ANNEXURE(S):

| Annexure no.    | Title of Annexure                              | Format No. | Mode of execution |
|-----------------|--|------------|-------------------|
| Annexure - I    | FBD finger bag inventory record                |            | Log book          |
| Annexure – II   | RMG filter bag inventory record                |            | Log book          |
| Annexure - IIII | FBP finger bag inventory record                |            | Log book          |
| Annexure - IV   | Air Jet Micronizer filter bag inventory record |            | Log book          |

# 9.0 **DISTRIBUTION:**

**Master Copy** : Quality Assurance

Controlled Copy (S): Production department (2), Quality Assurance (1)

**Reference Copy (S)**: Production department (2)

# 10.0 RIVISION HISTORY:

| S.No. | Version No. | Change<br>Control No. | REASON(S) FOR<br>REVISION | DETAILS OF<br>REVISION | Effective<br>Date |
|-------|-------------|-----------------------|---------------------------|------------------------|-------------------|
| 01    | 00          | NA                    | New SOP                   | NA                     | NA                |





|                        |                   |                      | STANDARD OP                  | ERATING 1    | PROCEI    | OURE              |               |             |         |         |
|------------------------|-------------------|----------------------|------------------------------|--------------|-----------|-------------------|---------------|-------------|---------|---------|
| Depar                  | tment: Production |                      |                              |              |           |                   |               | SOP No.:    |         |         |
| <b>Title:</b> filter b |                   | ge of FBD/FBP Finger | r Bag / RMG filter Bag / Air | Jet Microniz | er Filter | Bag / Air je      | et micronizer | Effective I | Date:   |         |
| Super                  | sedes: Nil        |                      |                              |              |           |                   |               | Review Da   | ate:    |         |
| Issue l                | Date:             |                      |                              |              |           |                   |               | Page No.:   |         |         |
|                        |                   |                      | ANNEX                        | KURE I       |           |                   |               |             |         |         |
|                        |                   |                      | FBD FINGER BAG IN            | NVENTORY     | RECO      | RD                |               |             |         |         |
| Department: FBD Model: |                   |                      |                              |              |           |                   |               |             |         |         |
| Depai                  | rtment:           |                      |                              |              |           |                   |               | FBD Mo      | odel:   |         |
| S.No.                  | Date of Receipt   | FBD Finger Bag       | Supplier Name                | Quantity     | Visual 1  | Inspection        | Checked<br>By | Scrapped    | Checked | Remarks |
|                        |                   |                      | Supplier Name                | Quantity     | Visual 1  | Inspection Not OK | Checked<br>By | T           |         |         |
|                        |                   | FBD Finger Bag       | Supplier Name                | Quantity     |           |                   |               | Scrapped    | Checked |         |
|                        |                   | FBD Finger Bag       | Supplier Name                | Quantity     |           |                   |               | Scrapped    | Checked |         |
|                        |                   | FBD Finger Bag       | Supplier Name                | Quantity     |           |                   |               | Scrapped    | Checked |         |





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| ANNEYLDE II  |                 |  |  |  |  |

# RMG FILTER BAG INVENTORY RECORD

| Deparu | ment:   |              |               |          |    |            |            | KWIG MOO    | iei:    |         |
|--------|---------|--------------|---------------|----------|----|------------|------------|-------------|---------|---------|
| S.No.  | Date of | RMG Filter   | Supplier Name | Quantity |    | Inspection | Checked By | Scrapped On | Checked | Remarks |
|        | Receipt | Bag Code no. |               |          | OK | Not OK     |            |             | Ву      |         |
|        |         |              |               |          |    |            |            |             |         |         |
|        |         |              |               |          |    |            |            |             |         |         |
|        |         |              |               |          |    |            |            |             |         |         |
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| Department: Production |                 |                            |                                  |              |          |                                 |              |                |               |         |
| Title: I filter b      | •               | ge of FBD/FBP Finger       | r Bag / RMG filter Bag / Air Jet | Micronizer l | Filter E | Bag / Air je                    | t micronizer | Effective      | Date:         |         |
| Supers                 | sedes: Nil      |                            |                                  |              |          |                                 |              | Review D       | ate:          |         |
| Issue I                | Date:           |                            |                                  |              |          |                                 |              | Page No.       | •             |         |
|                        |                 |                            | ANNE                             | XURE III     |          |                                 |              |                |               |         |
|                        |                 |                            | FBP FINGER BAG I                 | NVENTOR      | Y REC    | CORD                            |              |                |               |         |
| Depar                  | tment:          |                            |                                  |              |          |                                 |              | FBP M          | lodel:        |         |
| S.No.                  | Date of Receipt | FBP Finger Bag<br>Code no. | Supplier Name                    | Quantity     |          | Visual Checked<br>Inspection By |              | Scrapped<br>On | Checked<br>By | Remarks |
|                        |                 | Couc no.                   |                                  |              | 1112     | spection                        | Бу           | On             | ъy            |         |
|                        |                 | Couc no.                   |                                  |              | OK       | Not OK                          | Бу           | On             | Dy            |         |
|                        |                 | Code no.                   |                                  |              |          |                                 | Бу           | On .           | Dy .          |         |
|                        |                 | Code no.                   |                                  |              |          |                                 | Бу           | OII            | Dy            |         |
|                        |                 | Code no.                   |                                  |              |          |                                 | Бу           |                | Dy            |         |
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## **ANNEXURE IV**

# AIR JET MICRONIZER FILTER BAG INVENTORY RECORD

| S.No. | Date of<br>Receipt | Micronizer filter<br>Bag Code no. | Supplier Name | Quantity | Visual<br>Inspection |           | Checked<br>By | Scrapped<br>On | Checked<br>By | Remarks |
|-------|--------------------|-----------------------------------|---------------|----------|----------------------|-----------|---------------|----------------|---------------|---------|
|       | P.                 |                                   |               |          | OK                   | Not<br>OK | J             | <u> </u>       | -3            |         |
|       |                    |                                   |               |          |                      |           |               |                |               |         |
|       |                    |                                   |               |          |                      |           |               |                |               |         |
|       |                    |                                   |               |          |                      |           |               |                |               |         |
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