



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Procedure for inventory and integrity checking of finger bags for production.	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for inventory and integrity checking of finger bags for production.

2.0 SCOPE:

The procedure is applicable for inventory and integrity checking of new finger bags in Production area.

3.0 RESPONSIBILITY:

Production: Officer /Executive/Assistant Manager.

HOD–Production.

4.0 PROCEDURE:

4.1 Integrity checking for new finger bags of FBD:

- 4.1.1 On receipt of intimation from warehouse, collect all the finger bags from the warehouse de-dusting area.
- 4.1.2 Check integrity of all fingers, between the fingers, outside area, inside of the fingers and also check all stitches of finger bags and incase of any rejection, return to warehouse for further action.
- 4.1.3 Check the FBD Finger bag certificate supplied by supplier and check the compliance against specification.
- 4.1.4 Keep all good finger bags in cabinet provided and label as “New finger bag” with supplier name and date of inventory.
- 4.1.5 Take Inventory of total Qty. with Serial No. after receiving of new finger bag and record in Annexure I.
- 4.1.6 Allot a Code No. to the individual finger bag before use for product.
- 4.1.7 Clean the new finger bag before use.
- 4.1.8 **NOTE:** Integrity checking of finger bag to be done after receiving new bag, issue the respective bag with date and identification number and record in Annexure-I.

4.2 Integrity checking during usage of finger bags of FBD:

- 4.2.1 Visually Check the integrity of the finger bag before and after completion of each batch and



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Procedure for inventory and integrity checking of finger bags for production.	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

record in respective BMR.

- 4.2.2 Check for any opening of stitches from outside and inside of the finger bag.
- 4.2.3 Check for any damage, stains from outside and inside of the finger bag.
- 4.2.4 If any unusual observation found then reject the finger bag and inform to QA for further checking.
- 4.2.5 **Frequency:** Integrity of FBD bag to be done every six month and record in Annexure-III.
- 4.2.6 **Note:** Check the RMG bag integrity along with respective FBD bag.
- 4.2.7 In case of any rejection of FBD finger bag and RMG filter bag observed during usage then record the same in Annexure - III with date of rejection and reason of rejection (attached the investigation report if any) and get it checked by Production and QA.
Frequency: Issuance/Rejection Record of FBD bag to be done before allotted for any product and when ever rejection done.

4.3 Storage:

- 4.3.1 Ensure that the cupboard is cleaned.
- 4.3.2 Ensure that dedicated FBD Bag with RMG Filter Bag (if applicable) covered with double polythene bags are kept separately in the cabinet with status label.
- 4.3.3 Issue dedicated FBD Bag with RMG Filter Bag (if applicable) for corresponding batch.
- 4.3.4 After completion of activity, clean the FBD Bag with RMG Filter Bag (if applicable) and keep it in polythene bags with status label.
- 4.3.5 Put the FBD Bag with RMG Filter Bag (if applicable) in the storage cabinet as per code number provided for storage of dedicated bags.

4.4 Cleaning:

- 4.4.1 Remove the bag from the Fluid bed dryer and filter bag of RMG.
- 4.4.2 Turn the fingers of the bag inside out and soak in sufficient amount of warm purified water in a S.S. container for 30 minutes.
- 4.4.3 Scrub each individual finger and filter bag of RMG with a nylon scrubber so as to remove any adhered material.
- 4.4.4 Rinse the finger bags twice in sufficient amount of Purified Water.
- 4.4.5 Finally rinse with sufficient amount of Purified Water.



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Procedure for inventory and integrity checking of finger bags for production.	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 4.4.6 Transfer the RMG filter bag to the FBD Bowl, hang the finger bag on the finger bag ring and dry the bags at temperature 80° to 90°C for 30 to 40 minutes.
- 4.4.7 Ensure that the bags are completely dried.
- 4.4.8 Remove the finger bag filter bag of RMG from the FBD bowl, and keep it in double polythene bags and labeled as “FBD/RMG BAG STATUS”. Tie the polythene bag properly and transfer the finger bag to the finger bag storage cabinet provided.
- 4.4.9 If the FBD finger bag and filter bag of RMG are not used within a month, then re clean the finger bag before use.
- 4.4.10 All new FBD bag and filter bag of RMG shall be cleaned as per the procedure mentioned from step 4.4.2 to 4.4.7 before use.
- 4.4.11 Record the same in the finger bag utilization and cleaning record as per the Annexure-II.

4.5 Precaution:

- 4.5.1 Don't keep FBD Bags with RMG Filter Bag (if applicable) in wet condition.

4.6 Storage

Put the FBD Bag and RMG Filter Bag (if applicable) in the storage cabinet as per code number provided below for storage of dedicated bags.

4.6.1 Procedure to be followed for allotting code no. of FBD bag.

- 4.6.1.1 Nine characters shall be considered as code no. of FBD bag, as follows:

X	YY	WWW	-	ZZ
1 st Character	2 nd and 3 rd Character	4 th , 5 th & 6 th Character	7 th Character	8 th & 9 th Character
Denote for Department	Finger bag for FBD	Capacity of FBD (Like: 250/500 Kg).	Hyphen	Serial No.

X: Indicates department code such as ‘P’ for Production.

YY: Indicates finger bag for FBD.

WWW : Indicates for Capacity of FBD

Example: PFB250-01

P : Stands for Production

FB :Stands for Finger Bag for FBD



PHARMA DEVILS
PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Procedure for inventory and integrity checking of finger bags for production.	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

250: Capacity of FBD in Kg.

- : Hyphen

01 : Serial no.

4.6.1.2 If any FBD bag is damaged, then replace the bag in same number with remark in annexure.

4.6.2 Procedure to be followed for allotting code no. of RMG filter bag

4.6.2.1 Ten characters shall be considered as code no. of RMG filter bag, as follows:

X	YYY	WWW	-	ZZ
1 st character	2 nd , 3 rd & 4 th character	5 th , 6 th & 7 th character	8 th character	9 th & 10 th character
Department Code	Filter bag for RMG	Capacity of RMG: 600/1200 ltr.	Hyphen	Serial No.

X : Indicates department code such as 'P' for Production.

YYY: Indicates filter bag for RMG.

WWW : Indicates Capacity of RMG in Liter.

Example: PRFB600-01

P : Stands for Production

RFB :Stands for filter bag for RMG.

600 : Stands for Capacity of RMG in Liter.

- : Hyphen

01 : Serial no.

4.6.2.2 If any RMG filter is damaged, then replace the bag in the same number with remark in annexure.

4.6.3 Procedure to be followed for allotting code no. of FBD bowl sieve

4.6.3.1 Eight characters shall be considered as code no. of FBD bowl sieve, as follows:



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Procedure for inventory and integrity checking of finger bags for production.	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

X	YYY	W	-	ZZ
1 st and 2 nd character	3 rd , 4 th & 5 th character	6 th character	7 th character	8 th & 9 th character
Department Code	FBD Bowl Sieve	Make : Alliance	Hyphen	Serial No.

X : Indicates department code of 'P' for Production.

YYY: Indicates FBD Bowl Sieve.

W : Indicates for Make : Alliance

Example: PFBSA-01

P : Stands for Production

FBS : Stands for FBD Bowl Sieve

A : Stands for Alliance

- : Hyphen

01 : Serial No.

5.0 ANNEXURE (S):

Annexure –I: Inventory, Integrity, Issuance of Finger Bag Record.

Annexure –II: Finger bag utilization and cleaning record.

Annexure –III: Finger Bag Integrity record.

Annexure –IV: FBD Bag / RMG Bag Issuance / Rejection Record.

6.0 REFERENCE (S):

Nil

7.0 ABBREVIATION (S) /DEFINITION (S):

BMR : Batch Manufacturing Record

FBD : Fluidized Bed Dryer

RMG : Rapid Mixer Granulator

SOP : Standard Operating Procedure.

Q.A. : Quality Assurance



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Procedure for inventory and integrity checking of finger bags for production.	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	----	----	New SOP	----