



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Quality Assurance	<b>SOP No.:</b>
<b>Title:</b> Scrap Management	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 1.0 OBJECTIVE:

To lay down a Procedure for Scrap Management.

### 2.0 SCOPE:

This SOP shall be applicable to Scrap Management for all Department of .....

### 3.0 RESPONSIBILITY:

**QA (Officer/Executive):** Preparation, Distribution (to Respective Departments), Revision, Retrieval & Destruction of this SOP.

**QA Manager:** Review, Approval, Training and Effective implementation of this SOP in all the applicable areas.

**Warehouse (Officer/ Executive):** Effective implementation of this SOP.

### 4.0 ACCOUNTABILITY:

**Head QA:** Authorization of this SOP & ensure Training and effective Implementation of SOP.

**Warehouse:** Ensure Effective Implementation of this SOP.

### 5.0 DEFINITIONS:

**Scrap:** Waste that either has no economic value or only the value of its basic material content recoverable through recycling

**Scrap management:** Manufacturers do not intend or plan to make scrap, but depending on the industry and the product, scrap is produced. Scrap may be sold as a revenue generating product. Scrap is stored in scrap collection trolleys and sent outside on daily basis.

### 6.0 PROCEDURE:

**6.1** Different types of Scrap are generated in the Plant. This Scrap includes Empty Containers, Gunny Bags, Plastic & Rubber Scrap, Used Polythene Bags/Used Disposable Hand Gloves/Shoe Covers/ Nose Masks/Lint Free Cloth, Paper Scrap, Scrap of Corrugated Box, Stationary/ Carton /Label, Scrap of Broken Glassware, Rejected Glass Vials/Ampoules, Rejected Flip Off Seal, LDPE Ampoules, LDPE



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Scrap, Plastic Bottles, Rejected Blister of QC Department and General Waste/Scrap generated in the Plant.

### 6.2 EMPTY CONTAINERS:

#### 6.2.1 Empty Fiber Containers of Raw Materials / Plastic Containers/Empty Reagent Bottles:

6.2.1.1 Deface the Label of Empty Fiber Containers of Raw Materials/Plastic Containers/Empty Reagent Bottles by destroyed or removed.

6.2.1.2 Empty Reagent Bottles shall be rinsed with Water, and water is drained in a Basin.

6.2.1.3 Affix the Scrap Status label as per after recording the details in **Annexure-I**.

6.2.1.4 Collected Poly Bags / Dust Bin shall be transferred to Scrap Collection trolleys after recording the details in “**Scrap Transfer Form**” in **Annexure-II**.

#### 6.2.2 Empty Gunny / PP Woven Bags:

6.2.2.1 Empty Gunny and PP Woven Bags of Raw / Packing Materials generated in warehouse shall be counted and recorded in “**Scrap Transfer Form**” in **Annexure-II** and transfer to Scrap Collection trolleys by affixing “**Scrap Status Label**” as in **Annexure-I**.

### 6.3 CORRUGATED BOX/PAPER SCRAP/STATIONARY/CARTON:

Collect scrap of Corrugated Box, Paper, Stationary and Carton from all the Departments. Tear into several pieces and collect in a Polythene Bag / Waste Bin.

6.3.1 Affix the **Scrap Status Label** after recording the details in **Annexure-I**.

6.3.2 Enter the details in “**Scrap Transfer Form**” in **Annexure-II** and transfer the Bags / Waste Bin to Scrap Collection trolleys.

### 6.4 BROKEN GLASS BOTTLES:

6.4.1 Collect the Scrap containing Broken Glass Bottles from Production or any other Areas in a HDPE container so that it cannot harm to any workmen or handler and affix the Scrap status Label after recording its details as per format “**Scrap Status Label**” as shown in **Annexure-I**.

6.4.2 Enter the details in “**Scrap Transfer Form**” as per **Annexure-II** and Transfer the Bag / Waste Bin to Scrap Collection trolleys.



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### 6.5 REJECTED EMPTY BLISTERS:

**6.5.1** Collect de-foil shredded scrap of Empty Blisters Pieces of Foils in a Polythene Bag/Waste Bin and affix Scrap Status Label as in **Annexure-I**, Enter the details in “**Scrap Transfer Form**” as in **Annexure-II** and shall be sent to Scrap Collection trolleys.

### 6.6 NON RECOVERABLE REJECTS GENERATED FROM INJECTION (SMALL VOLUME PARENTERALS/VIAL/AMPOULE/OPHTHALMIC PREPARATION) DEPARTMENT:

**6.6.1** Collect Primary and Secondary Packing Material (Glass Vials / Ampoules, LDPE Ampoules / Caps & LDPE Scrap, Plastic Bottles, Rubber Plugs, Flip Off Seals, Syringe) generated during De-Cartoning, Washing, Filling and Sealing, Inspection, Weight and Volume Variation, In process testing or Spillage in a separate Poly Bag / Waste Bin and affix **Scrap Status Label** as in **Annexure-I**.

**6.6.2** Collect the Scrap Cartons, Labels and shippers in a separate Poly Bag / Waste Bin and affix Scrap Status Label on it.

**6.6.3** Empty out the partial Filled or Filled Rejected Container(s) in a separate Container and discard the material as per Destruction SOP.

**6.6.4** The Poly Bag Containing Glass Vials/Ampoules, LDPE Ampoules/Caps & LDPE Scrap, Plastic Bottles, Rubber Plugs, Flip off Seals, Syringe and other Scrap shall be sent to Scrap Collection trolleys through “**Scrap Transfer Form**” as per **Annexure-II**.

**6.6.5** The scrap In-charge shall ensure that all the labels and tags on Glass Vials / Ampoules, LDPE Ampoules / Caps & LDPE Scrap, Plastic Bottles, Rubber Plugs, Flip off Seals, Syringe are shredded in a manner that all the label are destroyed or removed.

### 6.7 NON- RECOVERABLE REJECTS GENERATED FROM QC LABORATORY:

**6.7.1** Collect waste of Sampled Poly Bags, Broken Glass wares / Bottles / Vials / Ampoules / HDPE Ampoules/Plastic Bottles / Rubber Plugs and Flip off Seals generated during testing from QC in separate Poly Bags / Waste Bin and affix Scrap Status Label as in **Annexure- I**.



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**6.7.2** Collected Poly Bags / Waste Bin shall be taken to Scrap Collection trolleys by filling details in “**Scrap Transfer Form**” as in **Annexure-II**.

**6.7.3** The scrap In-charge shall ensure that all the labels and tags Poly Bags, Broken Glass wares / Bottles / Vials / Ampoules / HDPE Ampoules/Plastic Bottles / Rubber Plugs and Flip off Seals are shredded/de-foiled in a manner that all the label are destroyed or removed.

**6.7.4** Used Broth and Agar Media shall be treated as per Disposal of Media as per respective SOP.

### **6.8 EXPIRED CHEMICALS/REAGENTS BOTTLES:**

**6.8.1** Empty the contents of Expired Chemicals/Reagents and Solvent Bottles in a separate Container and dispose off the Contents as per respective SOP.

**6.8.2** Deface the Label of Chemical/Reagents Bottles by removing the label.

**6.8.3** Collect the Empty Containers/Bottles of Reagents in a separate Poly Bag/Waste Bin and affix the **Scrap Status Label** as in Annexure-I and sent to Scrap Collection trolleys after filling the details in “**Scrap Transfer Form**” in **Annexure-II**.

### **6.9 SCRAP GENERATED FROM ENGINEERING / PRODUCTION DEPARTMENT:**

**6.9.1** Collect Discarded Screens, Filters, Moulds & Valves, Nuts & Bolts and any Rejected Machine Parts in separate Poly Bags and affix label as in **Annexure-I**.

**6.9.2** Enter the details in “**Scrap Transfer Form**” as in **Annexure-II** and shall be sent to Scrap Collection trolleys.

### **6.10 GENERAL SCRAP (PLASTIC SCRAP/RUBBER SCRAP/USED POLYTHENE BAGS/USED DISPOSABLE/HAND GLOVES/USED SHOE COVERS/USED NOSE MASKS/USED LINT FREE CLOTH/TORNED APRONS, SLIPPERS, SHOES & CAPS) GENERATED IN THE PLANT:**

**6.10.1** Collect the Scrap mentioned above in separate Polythene Bags/Waste Bin.

**6.10.2** Affix the Scrap Status Label after recording the details in **Annexure-I**.



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**6.10.3** Enter the details in “**Scrap Transfer Form**” in **Annexure-II** and transfer the Bags / Waste Bin to Scrap Collection trolleys.

**6.11** Segregate the Bags containing Scrap received at **Scrap Collection trolleys** as per the nature of the Material mentioned below.

- (a) Glass
- (b) Plastic
- (c) Foil
- (d) Paper & others
- (e) Rejected Blister

**6.12** Person from HR Department shall Sign the Scrap Transfer Form after verifying Weight as mentioned in “**Scrap Transfer Form**” and keep it till its disposal.

**6.13** The Scrap containing Empty Blister shall be shredded by means of Shredder / Crushing Machine & filled in the Bag & placed at designated place for its disposal.

**6.14** In case of availability of any Filled Bottle / Vial / Ampoule / Blister / Coded & Uncoded Printed Label at Scrap Collection Point, Person shall immediately inform to Concerned Department / HR Department/Plant Head and Head QA.

**6.15** Scrap In charge shall ensure that the defoiling of all the waste primary packing material and container is done in a manner to destroy/remove all the labels.

**6.16** The defacing/de-foiling of all the scrap material and labels should be verified by Scrap In-charge or his representative, Security Person, Administration representative before loading of the scrap to any vehicle.

**6.17** “**Scrap Transfer Form**” shall be filed with Store Department and to be retained for Two Years.

### 7.0 ABBREVIATIONS:

HDPE	High Density Polyethylene
HR	Human Resources
Ltd.	Limited
LDPE	LDPE Low Density Polyethylene



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NRR	Non Recoverable Residue
P & A	Personnel and Administration
PP	Poly Propylene
ROPP	Roll on Pilfer Proof
S.No.	Serial Number

### 8.0 ANNEXURES:

Annexure No.	Title of Annexure	Format No.
Annexure-I	Scrap Status Label	
Annexure-II	Scrap Transfer Form	

### 9.0 DISTRIBUTION:

- Master Copy Quality Assurance Department
- Controlled Copy No. 01 Quality Assurance Department.
- Controlled Copy No. 02 Quality Control Department.
- Controlled Copy No. 03 Production Department.
- Controlled Copy No. 04 Human Resource Department (HR).
- Controlled Copy No. 05 Engineering Department.
- Controlled Copy No. 06 Warehouse Department (Store).
- Controlled Copy No. 07 Information Technology Department

### 10.0 REFERENCES:

- **Schedule M** - “Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.”
- **SOP Titled “Destruction of Rejected Raw Material, In-Process Material, Finished Product & Packaging Materials”.**

### 11.0 REVISION HISTORY:



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Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		



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### Scrap Material Label

## SCRAP MATERIAL

**TYPE OF SCRAP :** \_\_\_\_\_

**DEPARTMENT :** \_\_\_\_\_

**CHECKED BY :** \_\_\_\_\_ **DATE :** \_\_\_\_\_





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## SCRAP TRANSFER FORM

**DEPARTMENT:** \_\_\_\_\_

**DATE:** \_\_\_\_\_

**AREA** : \_\_\_\_\_

S.No.	Type of Scrap	No. of Containers/ Bags	Weight o Scrap	Label Defaced (Y/N)	Done By (Sign & Date)

**Checked By:**  
**Production Officer**  
(Sign & Date)

**Verified By:**  
**QA Officer**  
(Sign & Date)

**Received By:**  
**Warehouse Officer**  
(Sign & Date)