

PHARMA DEVILS

STANDARD OPERATING PROCEDURE		
Department: Quality Assurance	SOP No.:	
Title: Scrap Management	Effective Date:	
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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 Low Density Polyethylene



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QUALITY ASSURANCE DEPARTMENT

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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. 05Engineering 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".



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11.0 REVISION HISTORY:

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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ANNEXURE-I Scrap Material Label

SCRAP MATERIAL		
TYPE OF SCRAP: _		
DEPARTMENT : _		
CHECKED BY : _	DATE :	_



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	ANNEXURI SCRAP TRANSFI				
DEPARTMENT:		DATE:			
	of Scrap	No. of Containers/ Bags	Weight o Scrap	Label Defaced (Y/N)	Done By (Sign & Date)