STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Destruction of Raw material, In-Process material, Finished Product & Packaging materials	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down a Procedure for Destruction of Raw Material, In-Process Material, Finished Product & Packaging Materials.

2.0 SCOPE:

This SOP is Applicable for Destruction of Rejected / Expired, Raw & Packaging Materials, Rejected In-Process Material & Rejected/Recalled/Expired Finished Products at……..

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.

Head Production, Warehouse & QC: Effective Implementation of this SOP in respective area of Plant.

4.0 ACCOUNTABILITY:

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

5.0 DEFINITION:

Raw Material: It refers to Active Pharmaceutical Ingredient. It is considered as one of the main part of the drug which is responsible for the drug action. Main thing is that Accuracy and Precision are must for the raw materials which is used for making the API.

Packaging Material: Pharmaceutical packaging can be defined as the economical means of providing presentation, protection, identification, information, convenience, compliance, integrity and stability of the product.

Finished Product: Finished Product is defined as the medicinal product that has undergone all stages of production, including packaging in its final container. The specifications for release of the finished product must comply with the FDA regulations. The specifications of the finished product at manufacture may be different from those of the medicinal product at expiry.

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6.0 PROCEDURE:

6.1 Destruction of the Raw Material/Packaging Materials/In-Process Material/Finished Products may be required in the following cases:

6.1.1 Shelf life of material is over.

6.1.2 Small Quantity of Material, which is not to be used.

6.1.3 Any Non-moving Material.

6.1.4 Material rejected by QC.

6.1.5 Contaminated Product.

6.1.6 RR of Product, which is discontinued from the further Production.

6.1.7 RR of Product colour of which is changed.

6.1.8 RR of Product, which cannot be recovered.

6.1.9 Any Raw Material if spilled on the floor and is not recoverable.

6.1.10 Recalled Products, which have failed in the specification and for which decision for destruction is made.

6.1.11 Goods returned from market and which are not suitable for sale.

6.1.12 Change in specification of materials, which makes the existing material not suitable for use.

6.2 Concern department takes Pre-Approval by mail with PPIC Head/QA Head/Purchase Head/Plant Head for Destruction.

6.3 After approval concern department make destruction note in ERP as per screen short.

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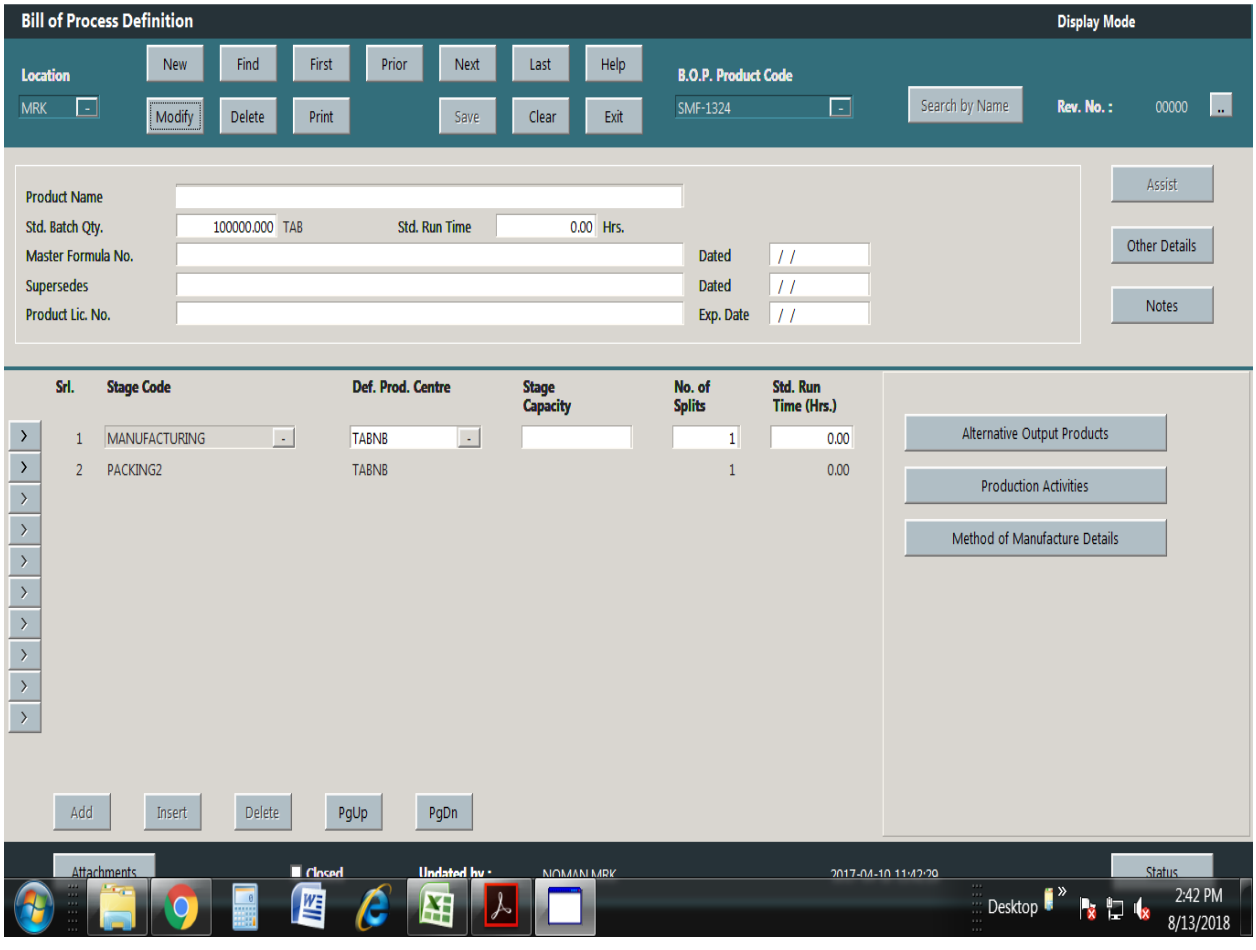

6.4 Take the print of Destruction Note (shown in **Annexure-I)** & Certificate (shown in **Annexure-II)** from ERP generated format take the signature of all concern department and after that start signature process.

6.5 Mode of Destruction:

6.5.1 Rejected/Expired Raw Materials and Rejected Inprocess Materials:

6.5.1.1 Rejected Raw Material/Inprocess Materials shall bring along with Authorized **"Destruction Note"**, to the Material destruction Area in Double lined Polybags affixed with Status Label.

6.5.1.2 Rejected Materials shall be transferred into SS container and treated with 10% NaOH Solution in **1:5** ratios for neutralization.

6.5.1.3 After neutralization resulting slurry shall be sent to the ETP for disposal.

6.5.1.4 Label of Empty containers shall be defaced by cross marking with Permanent marker.

6.5.1.5 Empty containers treated with 10% NaOH Solution, and shall be sent to Scrap Yard.

6.5.2 Rejected/Recalled/Expired Finished Product:

6.5.2.1 Rejected/Recalled/Expired finished Product to be destroyed shall bring along with Authorized **"Destruction Note"**, to the Material destruction Area in Double lined Polybags affixed with Status Label.

6.5.2.2 Printed Materials and empty shippers shall be separated from the finished goods and subjected to destroy as per destruction of rejected Printed Packaging Materials as defined in point no. **6.5.3**.

6.5.2.3 Primary packing shall be opened carefully and the material shall be kept in SS container and treated with 10% NaOH solution in **1:5** ratio for neutralization.

6.5.2.4 After neutralization resulting slurry shall be sent to ETP for disposal.

6.5.2.5 Container/Vials/Ampoules shall be treated with 10% NaOH Solution and shall be sent to scrap yard after crushing.

6.5.2.6 Rubber closures/Bungs shall be shredded into pieces and shall be sent to scrap yard.

6.5.2.7 Aluminium Seal Caps shall be shredded into pieces and shall be sent to scrap yard.

6.5.2.8 Empty Blisters/Strips shall be shredded into pieces and shall be sent to scrap yard.

6.5.3 Rejected Packaging Materials:

6.5.3.1 Rejected Packaging Materials to be destroyed shall bring along with copy of Authorized **"Destruction Note"**, to the Material destruction Area in Double lined Polybags affixed with Status Label.

6.5.3.2 Rejected Packaging Materials shall be shredded into small pieces and send to Scrap Yard.

6.6 Original copy of Destruction Note with Destruction Certificate shall be retained with QA Department for record.

6.7 Send copy of destruction note to Accounts Department, Head PPIC & Plant Head and attach a copy of it with BMR & BPR of respective batch or relevant Document.

6.8 All Destruction Note shall be retained by QA for **5 Years.**

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7.0 ABBREVIATIONS:

A.R. No.	Analytical Reference Number
ETP	Effluent Treatment Plant
Ltd.	Limited
No.	Number
PPIC	Production Planning & Inventory Control
Pvt.	Private
QA	Quality Assurance
QC	Quality Control
RR	Recoverable Rejects
SAP	Systems, Applications & Programme in Data Processing
SOP	Standard Operating Procedure
SS	Stainless Steel

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Destruction Note	
Annexure-II	Destruction Certificate	
Annexure-III	Destruction Log Book	

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).

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10.0 REFERENCES:

Not Applicable

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

Destruction Note No. : _____ **Date:** _____
Product / Material Name : _____
Manufacturer / Supplier : _____
Batch No. / G.R. No. / A.R. No.: _____
Quantity / Unit : _____
Reason for Destruction : _____
Mode of Destruction : _____

Initiated By:	**Checked By:**	**Checked By:**	**Approved By:**
Department:	Department Head:	PPIC Head:	Head QA:
Name:	Name:	Name:	Name:
Sign & Date:	Sign & Date:	Sign & Date:	Sign & Date:

DESTRUCTION VERIFICATION REPORT

Material Destruction On: _____

Material Destruction By
Department:
Name:
Sign & Date:

Verified By (QA)
Name:
Sign & Date:

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ANNEXURE-II

This is to certified that below mentioned item/items has been destroyed in presence of Authorized Personnel from QA Department.

S. No.	Material Description	Destruction Note No.	Destruction Date	Batch No.	Quantity/ Unit	Reason for Destruction	Mode of Destruction

Approved By
Head QA
Sign & Date

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ANNEXURE-III

S.No.	Material	Destruction Date	Batch No.	Quantity/ Unit	Reason for Destruction	Remark