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1. Purpose

The purpose of this SOP is to lay down the procedure for disposal of expired, damaged, near expiry, recalled and sales return products and stability, reference samples received from Sales Depots (Stock Points) QA/Regulatory departments at CWH.

2. Scope

This Standard Operating Procedure is applicable to Extended Warehouse.

3. Definitions

3.1 This Standard Operating Procedure (SOP) is an authorized written procedure, providing instructions.

3.2 Abbreviations

CWH	Central Warehouse
QA	Quality Assurance
PPE	Personal Protective Equipments
SHE	Safety Health and Enviornmentment
AZ	AstraZeneca
SHE	Safety Health and Environment
GLF	Global logistics function

4. Responsibilities

Activity	Responsibility
Receiving of the stocks and documentation, obtaining approval for destruction, Sending the waste for incineration	Trained Warehouse staff
Ensure Compliance	Supplier Relations Manager / Logistics Manager / Director- Distribution / GLF - QA or Deputy.

5. Procedure

- 5.1 Receive the broken / damaged / expired / market returns/ sales return/near expiry goods from sales Depots (storage locations) and expired reference samples and stability samples from QA/regulatory department and record manually in “Register of Breakages/Expired details of stock receipt from Depot/CFA and incineration details-Annexure-1”. (Destruction certificate shall be issued on demand from Depots).
- 5.2 Check the stocks as per Form-0101739 “Form for Verification of Returned Stocks” for Batch and quantity authentication.
- 5.3 Remove and Segregate Blister, Strip, Bottles, Ampoules, Vials, Syringes, Inhalers and deface all these items. Defacing should be done by scoring out (like cross mark) printed matter using a permanent marker pen. Ensure tamper evident seals are removed. These defaced items to be kept in designated area for further destruction process.
- 5.4 Literatures/Pack Inserts/Carton boxes shall be separated as paper waste, shred and send the same to scrap yard as paper waste.
- 5.5 Product labels on shippers shall be defaced. Defacing should be done by scoring out (like cross mark) printed matter using a permanent marker pen.
- 5.6 Obtain approval for destruction as per FORM-0040581 on approval for Dispatching Segregated Stocks for Incineration as Hazardous stock.
- 5.7 Arrange for transportation periodically of segregated materials through approved vendor for incineration.
- 5.8 Arrange for necessary weighment of Vehicle before and after loading.
- 5.9 Fill necessary forms as required by SHE (Form 10 and TREM Card) to be accompanied in the consignment and non-returnable gate pass. Follow waste management procedure SOP-0105334.
- 5.10 AZ Security shall accompany the vehicle transporting the hazardous waste and supervise the unloading at the designated room provided by the service provider for storing AZ Hazardous waste till incineration.
- 5.11 Security Guard shall ensure locking of the AZ designated room and carry key to AZ Security custody once the unloading is over.
- 5.12 On getting the confirmation for incineration of hazardous stock, the AZ Security shall go to incinerator premises and supervise till all our products got incinerated.
- 5.13 Once the Incineration process is over, follow up for Destruction Certificate.
- 5.14 Collect the destruction certificate and file it along with relevant documents.

- 5.15 Initiate stock count for stocks being dispatched for incineration and on receipt of destruction certificate update the stock count number in the destruction certificate.
- 5.16 During segregation process wear necessary PPEs like gloves, goggles, mask, safety shoes, etc
- 5.17 Security marshals accompanying the disposal stock for observed destruction would be on a rotational basis.

6. References

- 6.1 Waste Management SOP No. SOP-0105334.

7. Change History

This Document differs from the previous version in the following way(s)

- 7.1 Defacing procedure elaborated in point no.5.3 & 5.5.
- 7.2 EQV system Nos has been updated for all the reference checklist and SOP.
- 7.3 Editorial change without change meaning

8. Annexure

Annexure-1- Breakages/Expiry details of stock receipt from Depot/CFA and incineration.

Annexure-1

AstraZeneca Pharma India Limited, Extended Warehouse, Yelahanka, Bangalore.
Breakage/expiry: Details of stock receipt from Depot/CFAs and incineration details

(Refer SOP No. SOP-0047309)

Month:

Sl. No.	Goods Received from	Goods Received on	Goods Despatch Note		Consignment Note		No. of CBs Received	Stock count Number	Date of approval obtained for incineration
			No	Date	No	Date			

Goods sent for incineration on	Gate Pass		Goods Incinerated on	Certificate		
	No	Date		No	Date	Sent to Depot/CFA on

Document Approvals

Quality Approval	Mahesh Venkatachalapathy Mahesh.Venkatachalapathy@astrazeneca.com 15-Sep-2022 09:52:21 GMT+0000
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