1.0 PURPOSE

1.1 This document lays down the procedure for product recall.

1.2 This procedure is intended for warehouse staff to ensure prompt and efficient recall of products known or suspected to be defective from the market. It applies to all finished pharmaceutical products.

1.3 The Pharmacist shall be responsible for update of this procedure.

1.4 The Warehouse Project Manager shall ensure this procedure is activated and executed upon receiving product recall instruction.

2.0 SCOPE

2.1 This procedure is applicable to all SMSA warehouse personnel working within the Healthcare Warehouse and assigned to receive, dispatch, storage, and deliver drug products.

3.0 ABBREVIATIONS/DEFINITION

No.	Term	Description
3.1	SFDA	Saudi Food and Drugs Administration
3.2	NUPCO	National Unified Procurement Company for Medical Supplies
3.3	MOI	Ministry Of Interior
3.4	SOP	Standard Operating Procedure
3.5	KSA	Kingdom of Saudi Arabia
3.6	TV	Television
3.7	CAPA	Corrective Action Preventive Action

4.0 RESPONSIBILITY

4.1 It is the responsibility of Project manager, and Pharmacist to execute and implement the Procedure.

	Name & Designation	Signature
Author/ Originator of Doc Change	MOAYAD MOHAMEDAIN PHARMACIST	29-05-2025
Reviewer (Process Owner)	M. Jamil Jameel Warehouse Supervisor	31/05/2025
Approving Authority	Project Coordinator	

5.0 PROCEDURE

5.1 During a product recall, the procedure shall be followed as defined in Flow Chart A.

5.2 Flow Chart Note:

5.2.1 Upon receiving a product recall in any of the below-mentioned situations, the pharmacist activates and executes the product recall:

5.2.1.1 A recall instruction from the manufacturer / product owner through NUPCO/MOI or SFDA.

5.2.1.2 A recall instruction from the Warehouse Manager in response to any serious product complaint or any in-house detected serious defective product and it is determined by the Pharmacist, in consultation with the manufacturer, that the product is not suitable for consumption.

5.2.1.3 Pharmacist shall fill all the details in Annexure – A and Annexure – B of the same SOP.

5.2.1.4 A recall order from local regulatory authority, such as SFDA, KSA.

5.2.1.5 Sending email to NUPCO to Inform all customers about Recall items.

5.3 Recall Classification

5.3.1 During recall of the product from the market recall classification should be done by taking the following point in consideration:

5.3.1.1 Whether or not any disease or injuries have already occurred from the use of the product.

5.3.1.2 Assessment of hazard to various segments of the population, e.g., children, surgical patients etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk

5.3.1.3 Assessment of the degree of seriousness of the health hazard to which the population at risk would be exposed.

5.3.1.4 Where the problem is of a health and safety concern, consultation with the regulatory Agency shall be done to ensure that action/decision taken is correct.

5.4 Type of Classification:

5.4.1 **Class 1:** When there is an emergency situation involving removal from the market of products in which the consequences of use or exposure to the product are life threatening or involve a serious adverse health consequence, this will involve contact with wholesalers/distributors, pharmacists and medical practitioners and possibly the consumer. A public announcement (newspaper, radio, TV) may also be required.

5.4.2 Class 2: When there is a situation in which the use of, or exposure to, a violated product may cause temporary adverse health consequences or where the probability of serious adverse health consequence is remote. A recall shall be initiated involving contact with wholesale dealers/distributors, and possibly pharmacist.

5.4.3 **Class 3:** When there is a situation in which the use of, or exposure to the product is not likely to cause adverse health consequences. Example: labelling violations. Further distribution of the defected product (batches) may be discontinued, and product shall be recalled and stored in separate dedicated area.

5.5 Recall product shall be kept in hold till the completion of the Investigation, root cause of the recall shall be found out and CAPA shall be implementing.

6.0 RECORD

Title of Record	Custodian	Retention Period
Product Recall Report	Pharmacist	7 Years
Recall Letter	Pharmacist	7 Years

7.0 Attachment

7.1 Flow Chart A

7.2 Annexure – A

7.3 Annexure – B

	Name & Designation	Signature
Author/ Originator of Doc Change	MOAYAD MOHAMEDAIN PHARMACIST	29-05-2023
Reviewer (Process Owner)	M.J.M Jareed Warehouse Supervisor	31/05/2023
Approving Authority		

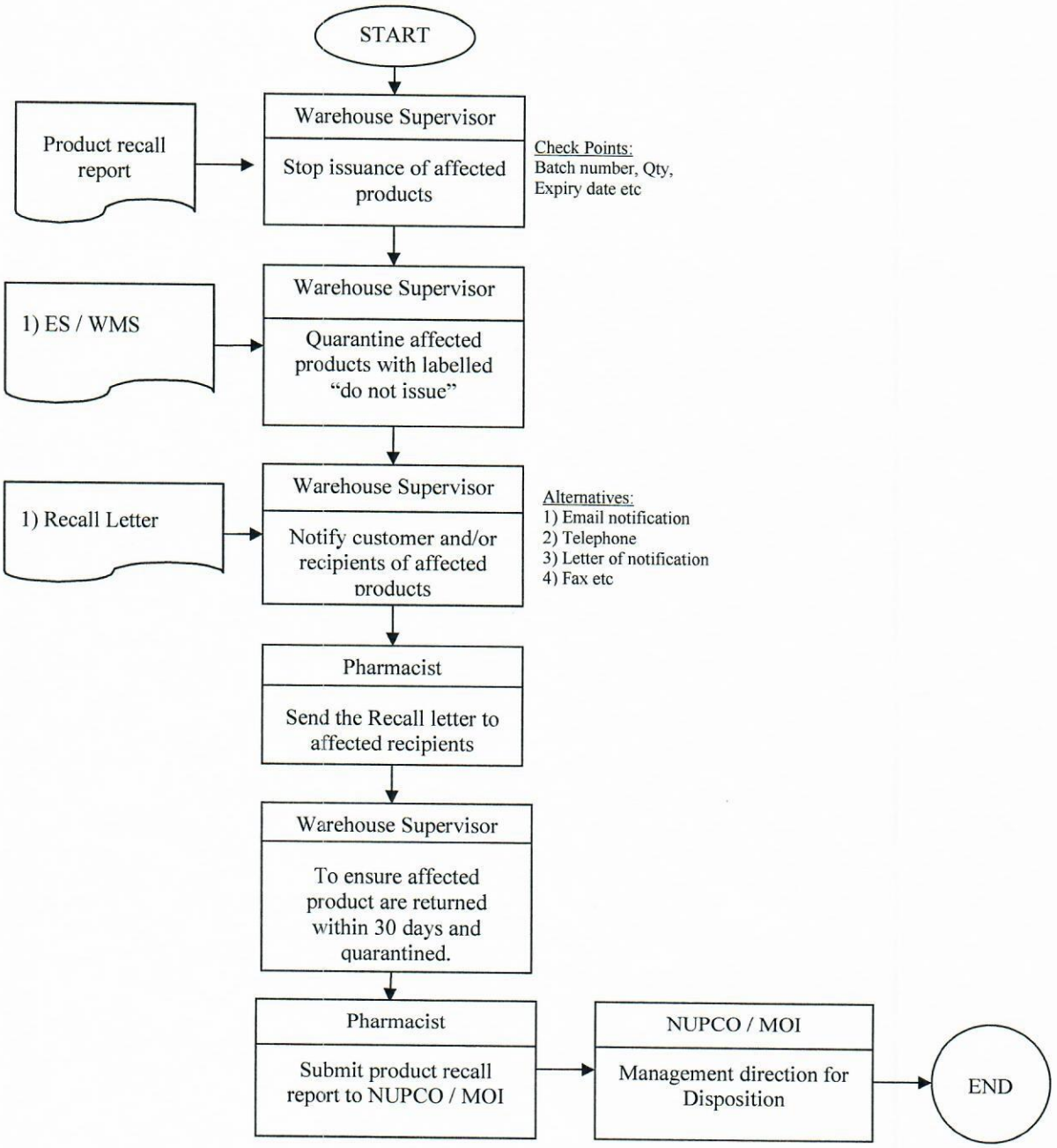
8.0 DOCUMENT CHANGE RECORD

Rev No.	Effective Date	Nature of Change	Document Change Request No:
00	30-11-2016	New Document	NA
01	26-01-2017	Point 5.3, 5.4, 5.5 incorporated for Classification of Recall and type of classification of Recall.	CR0091
02		Changes Made in SOP as follows: • SOP Document ID amended as SMSA-HC unique ID format for all SOP. • Incorporated abbreviations under section 3 as used in SOP. • Amended point 5.2.1.1. By explaining the receiving of product recall. • Amended the Flow Chart A by adding Notify customer and/or recipients of affected products.	
03	01-05-2023	• 5.2.1.5 incorporated Sending email to NUPCO to Inform all customers about Re call items	

	Name & Designation	Signature
Author/ Originator of Doc Change	MOAYAD MOHAMMEDAIN PHARMACIST	29-05-2025
Reviewer (Process Owner)	M. J. M. Joreon Warehouse Supervisor	29/05/2025
Approving Authority		

Flow Chart A

RECALL PROCEDURE



Annexure-A

(TO BE USED IN CONJUNCTION WITH SOP No. SMSA-12)

RECALL COMPLAINT FORM

1. **Complaint Notification procedure:** **Oral** ☐ **Written** ☐
2. **Date of the complaint:** _____
3. **Product Name, Strength & Dosage form:** _____
4. **Packaging type & size:** _____
5. **Batch No #** _____
6. **Mfg. and Exp. Date :** _____
7. **Invoice no.:** _____
8. **Recall Complaint source:** _____
9. **Name:** _____
10. **Address:** _____
11. **Defective Sample availability:** **Yes** ☐ **No** ☐
12. **Nature of complaint (Description):**

_____

_____

_____

_____

Filled By: _____ Date: _____

Annexure-B

(TO BE USED IN CONJUNCTION WITH SOP No. SMSA-12)

RECALL INVESTIGATION REPORT

1. **Product Name:** _____
2. **Product Name, Strenght, and Dosage Form:** _____
3. **Batch No. #** _____
4. **Nature of complaint:** _____

   _____
5. **Number of consignees notified of the recall.**
6. **Number of consignees responding to the recall communication.**
7. **Number of consignees that didn't respond (if needed, the identity of non responding consignees maybe requested by local authority).**
8. **Number of products returned or corrected by each consignee contacted and the quantity of products accounted for**
9. **Number and results of effectiveness checks that were made.**
10. **Estimated time frames for completion of the recall.**
11. **Original Recall Complaint initiated by:** _____
12. **Supplier informed about the Recall issue?:** _____
13. **Recall Process conclusion:**

_____

_____

_____

_____

_____

_____

Prepared by: _____ **Date:** _____

Project Manager: _____ **Date:** _____