1.0 PURPOSE

1.1 This document lays down the procedure for all product complaints for pharmaceutical products.

1.2 This procedure is to provide a system for documentation and timely response to customer complaints as well as addresses findings from warehouse stock check for product's quality related problems.

2.0 SCOPE

2.1 This procedure is applicable to all SMSA Employee working with pharmaceutical Warehouse and handling the Product Complaints.

3.0 ABBREVIATIONS/DEFINITION

No.	Term	Description
3.1	NUPCO	National Unified Procurement Company for Medical Supplies
3.2	MOI	Ministry Of Interior
3.3	NC	Non-Conformance/Conformity
3.4	QRM	Quality and Risk Management
3.5	&	And
3.6	SOP	Standard Operating Procedure

4.0 RESPONSIBILITY

4.1 The Warehouse Pharmacist shall be responsible for update for this procedure, handles product complaints, and in consultation/discussion with Project Manager, and if required, seek advice from NUPCO/MOI to decide on the corrective action to be taken according to this procedure.

4.2 The Warehouse Manager shall ensure this procedure is activated and executed upon receiving product complaints both by NUPCO/MOI and operations staff during stock check, to fill up Product Complaints Report and forward it to the Pharmacist.

5.0 PROCEDURE

5.1 Upon receiving NUPCO/MOI complaints via Email or any letter and/or returning of goods relating to product deficiencies/or findings from warehouse stock check, such as quantities different from labels, defective

containers, labeling and batch error, a Product Complaint Report (see attached Annexure A) shall be initiated first as per details provided in complaint from NUPCO/MOI via Email or any letter .All product Complaint shall be received via Email or any letter from NUPCO/MOI and then it will be forwarded to QRM department to raise an NC for the product complaint to make it centralized. Also the analysis of the product complaint shall be done as stated in point 5.7 of this SOP.

5.2 Customer (NUPCO/MOI) details such as name, address and contact number, product detail such as batch number, quantity involved in the nature of complaints are to be recorded in the Product Complaints Report.

5.3 The Pharmacist shall investigate the complaints of the affected / returned products, for its source of supply, date of receipt and whether the existing stock and other batches (batch before & batch after) are similarly affected, to establish the seriousness and extent of the problem.

5.4 For products with minor defects, affecting small and limited quantities of stocks, the pharmacist shall discuss with Warehouse Project Manager to decide on the corrective action to be taken to prevent recurrence.

5.5 If investigation reveals serious problem which warrants product recall and the NUPCO/MOI is informed, and Procedure on Product Recall to be executed.

5.6 The outcome of investigation and the decision or measures taken on product complaints is to be recorded on Product Complaints Report.

5.7 Product complaints records and their corrective actions are to be reviewed quarterly by the Warehouse Manager or Pharmacist for any indication of specific or recurring problems that may require higher management attention. Also after review of Product complaint an analysis shall be done in order to check the trend of complaints and shall share with QRM. If higher management attention require, it will be discussed and recorded in Management Meeting.

5.8 The NUPCO/MOI will be notified within 24 hours.

6.0 RECORD

Title of Record	Custodian	Retention Period
Product Complaint Report	Pharmacist	5 Years

7.0 Attachment/Reference

7.1 Annexure A – Product Complaint Report

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

8.0 DOCUMENT CHANGE RECORD

Rev No.	Effective Date	Nature of Change	Document Change Request No.
00	28-11-2016	New document	NA
01	06-02-2018	Changes Made in the SOP as follows • SOP Format updated to uniform all SOPs. • SOP Document ID amended as SMSA-HC unique ID format for all SOP. • Incorporated abbreviation under section 3 as used in SOP. • Amended point 4.1 and 4.2 by adding responsibility of assistant manager instead of supervisor and customer/Manufacturer replaced with NUPCO/MOI. • Amended all SOP by replacing customer or manufacturer by NUPCO/MOI as actual. • Amended point 5.1 by adding the procedure for centralizing the Complaints. • Amended point 5.7 for review period from semiannually to quarterly and explain the procedure of analysis of complaints.	
02	05-02-2020	• Amended point 5.4 by removing the NUOCO/MOI will be informed if required. • Incorporated point 5.8 The NUPCO/MOI will be notified within 24 hours.	

END OF THE DOCUMENT

	Name & Designation	Signature
Author/ Originator of Doc Change	MOATAZ MOHAMED HAN PHARMACIST	29-05-2025
Reviewer (Process Owner)	M.S.M. Jareed Warehouse Supervisor	31/05/2025
Approving Authority		

Product Complaint Report

ANNEX A

Date: _____

Customer Name	
Customer Address	
Customer Contact No.	

1. PRODUCT COMPLAINT

Product Description	Lot/ Batch No	Quantity	Nature of Complaint
Complaint received and recorded by:			
Name & Signature:			

2. INVESTIGATION AND OUTCOME / RECOMMENDATION

Investigated by:	
Name & Signature:	

3. CORRECTIVE ACTION TO BE TAKEN

Authorised by:	
Name & Signature:	

4. REVIEW OF PRODUCT COMPLAINT REPORTS RECORD

Reviewed and recommendation made by:		Date
Name & Signature:		
Approved by:		Date
Name & Signature:		