1.0 PURPOSE

1.1 To lay down the procedure for Quality system for pharmaceutical Warehouse.

2.0 SCOPE

2.1 This procedure is applicable to all the personnel working in SMSA pharmaceutical Warehouse.

3.0 ABBREVIATIONS/DEFINITION

No.	Term	Description
3.1	SOP	Standard Operating Procedure
3.2	GDP	Good Distribution Practice
3.3	PPE	Personal Protective Equipment
3.4	°C	Degree Celsius
3.5	e.g.	For example,
3.6	No.	Number
3.7	NUPCO	National Unified Procurement Company for Medical supplies.
3.8	MOI	Ministry of Interior

4.0 RESPONSIBILITY

4.1 It is the responsibility of the SMSA Project Manager, Assistant Project Manager and Pharmacist to implement the procedure.

4.2 It is the responsibility of all the employees to follow and maintain the Quality system working in SMSA Pharmaceutical Warehouse.

5.0 PRECAUTION/INSTRUCTION

5.1 All SMSA employees shall follow the Quality System for Pharmaceutical warehouse to maintain the quality of the Medicines.

5.2 All SMSA employees shall wear the PPEs to avoid any contamination to the Pharmaceutical Items or Personnel.

	Name & Designation	Signature
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Reviewer (Process Owner)	M.J.M. Jaheed	

6.0 PROCEDURE

6.1 SMSA Shall identifies the required infrastructure to provide conforming pharmaceutical products. The SMSA Warehouse shall design with suitable storage conditions to meet the requirements of pharmaceutical products and medical devices. The storage arrangements in the warehouse shall design to prevent contamination and undue deterioration to the products such as direct sunlight and rainwater penetration.

6.2 Only authorized personnel are allowed access to the SMSA Warehouse the following

6.2.1 Staff working at the warehouse is issued with SMSA ID.

6.2.2 Any Visitor shall report to Security and wait for the person to whom he or she wants to meet in Visitor's Room. If visitor allowed visiting inside the Warehouse, he or she shall be accompanied by SMSA Staff.

6.2.3 Unauthorized personnel are not allowed into the warehouse.

6.3 The SMSA Warehouse shall be backed up by emergency power supply to maintain the quality of pharmaceutical product kept inside the warehouse. In case of external power supply failure, the backed-up emergency power supply will cut in to and supply the electrical power to the air-conditioned warehouses and Cold and Freezer rooms as well.

6.4 The overall temperature level maintained in the SMSA Pharmaceutical Warehouse shall between 15°C to 25°C. For Cold Room and Freezer room the temperature to maintain shall be 2°C to 8°C and -1°C to -17°C respectively. The temperature level shall be monitored and recorded for all the areas.

6.5 The cleaning and sanitization of the SMSA warehouse shall be performed daily, weekly, monthly or whenever required as per Cleaning SOP and the cleaning checklist shall be documented to maintain the hygiene and quality of Pharmaceutical.

6.6 Storage of Pharmaceutical Items

6.6.1 The warehouse shall ensure storage of all products is in good state of cleanliness and no products are allowed to be stored on the floor. In the event that any pharmaceutical items need any special storage other than racking and shelves, it shall be stored in accordance to its specified Storage condition. Material of different status, e.g. Expired, Reject or damaged shall physically segregated from serviceable stock.

6.6.2 Designated areas shall mark for Expired, Damage and rejected stock with Signages "Expired, Damage or rejected". The affected stock in the accounting system is "Blocked Stock" or "Restricted" to prevent any issues.

6.6.3 The pest control program shall outsource to a servicing agent for monthly Pest control program and monitored by the Warehouse Project Manager, Assistant Project Manager or Pharmacist.

6.7 Receiving and Handling of Pharmaceutical Items

6.7.1 Receiving of Pharmaceutical Items and its incoming inspection shall perform at the designated area as per Receiving SOP and mandatory checks e.g. Item Code, description, Batch No., Expiry Date, Quantity with respect to Order/Invoice.

6.7.2 Receipt of cold chain products shall be performed in the designated cold room to maintain the product's cold chain requirement or storage condition.

6.7.3 All goods in their packing shall be inspected for possible tempering, contamination and damage in the presence of suppliers/Drivers. Any discrepancies or damage goods will be rejected and documented.

6.7.4 Any incoming products on hold or quarantine shall only be released as usable products for storage by the written authority from the customers.

6.8 Delivery and Transportation of Products

6.8.1 Pharmaceutical Items to meet customer requirements shall picked and to be ready for delivery at designated issue area.

6.8.2 All outgoing shipments shall be inspected prior to item's delivery, to ensure item's Quality e.g. Item Code, description, Batch No., Expiry Date, Quantity with respect to Order.

6.8.3 All the shipments shall deliver to customer in temperature controlled Vehicles and records of in transit temperature shall be maintained as per in-transit temperature monitoring SOP.

6.9 Stock Control

6.9.1 Records for the incoming pharmaceutical items shall be accounted in the 3PL Central Warehouse Management System (WMS). Product Quantity, Shelf-Life, Batch / Lot Number and Expiry Date are mandatory data in the accounting system and records. Pharmaceutical items with shelf life are issued base on "First-Expired- First- Out (FEFO)," as automated process by the system.

6.9.2 Cycle count shall document in procedure to ensure physical stock accuracy and condition of items.

6.10 Product Recall

6.10.1 Documented procedure on Product Recall shall laid down the requirement for product recall and describes the sequence of actions to follow including:

- 6.10.1.1 Retrieval of distribution data
- 6.10.1.2 Notification of customers
- 6.10.1.3 Receipt / segregation/inspection of returned products
- 6.10.1.4 Investigation/reporting of Route cause
- 6.10.1.5 Reporting Corrective Action, Preventive Action.

6.10.1.6 The pharmacist shall responsible for coordinating product recall and report to Project Manager or Assistant Project Manager for the requirement on follow up corrective action, Preventive action

6.10.1.7 The pharmacist is to notify the NUPCO/MOI who will notify Competent Authority of complaints and recalls.

6.10.1.8 The company will act on the instruction from Competent Authority / or manufacturer for any product to be recalled.

6.10.1.9 Recall Product shall be separate from normal pharmaceutical Items in Recall area under lock and Key.

7.0 RECORD

Title of Record	Custodian	Retention Period
NA	NA	NA

8.0 Attachment

NA

9.0 DOCUMENT CHANGE RECORD

Rev No.	Effective Date	Nature of Change	Document Change Request No:
00	23-10-2016	New Document	NA
01	18-02-2018	Changes Made in SOP as follows: • SOP Document ID amended as SMSA-HC unique ID format for all SOP. • Incorporated abbreviations under section 3. • Amended point 6.3 by adding cold room and freezer room for backup supply. • Amended point 6.6.2 by adding signages for Expired, Damaged and rejected area. • Amended point 6.10.1.7 by adding NUPCO/MOI to be notifies.	

END OF DOCUMENT

	Name & Designation	Signature
Author/ Originator of Doc Change	MOAYAD MOHAMEDAW PHARMACIST	24-05-2025
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