1.0 PURPOSE

1.1 The purpose of this procedure is to lay down the procedure of Good Storage Practices in SMSA Warehouse to meet the operational requirements.

2.0 SCOPE

2.1 This procedure is applicable to all SMSA Employee working with pharmaceutical Warehouse.

3.0 ABBREVIATIONS/DEFINITION

No.	Term	Description
3.1	NMT	Not More than
3.2	°C	Degree Celsius
3.3	WMS	Warehouse Management System
3.4	SOP	Standard Operating Procedure
3.5	PPE	Personal Protective Equipment

4.0 RESPONSIBILITY

4.1 It is the responsibility of SMSA Project manager, Assistant Project Manager and Pharmacist to make sure that the storage area is always complies with the required specifications.

5.0 PROCEDURE

5.1 Pharmaceutical Products shall be stored in carton boxes on storage shelving. The product shall be clearly identified on carton box with bar code label indicating the following:

5.1.1 Product Number
5.1.2 Description
5.1.3 Lot Number
5.1.4 Expiry date.

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5.2 Pharmaceutical Products shall be stored on pallets to allow easy cleaning, inspection and retrieval. Pallets are to be well maintained and kept in good State of cleanliness.

5.3 Designated areas are identified to store different range of products. SMSA Warehouse work areas and layout are marked according to its work flow processes into: Inbound, Outbound, Storage and Quarantine Area.

5.4 Storage area should be of sufficient capacity and physical segregation (or other validated segregation should be provided) for the storage of:

5.4.1 Expired products area.

5.4.2 Damaged products area.

5.4.3 Returned/Rejected products area.

5.4.4 Quarantine products Area (for recalled and counterfeit products).

5.5 The heavy Pallets shall be placed or put away on lower or bottom shelves.

5.6 If any staff want to pick the items from upper most or the higher racks/Shelves, then he shall lower down the pallet from forklift and bring to the ground/floor for picking. If staff needs to pick from upper most or the higher racks/Shelves by not bringing down the pallet, then he shall follow all the safety instructions as he should wear the safety harness/Belt, he should wear safety helmet, the pallet shall be tied with the forks of forklifts in order to fix the pallet to not to move.

5.7 Storage method of quarantine products are identified as follows:

5.7.1 Ambient products are to be kept at the designated rack under appropriate strict safety and security measures and label 'Quarantine' with reason of quarantine to be clearly marked on the product.

5.7.2 Cold Chain products: To be quarantined at desired temperature with indication 'Quarantine 'the particular or specific location inside the Cold or Freezer room or in general 'Quarantine' area with temperature NMT 25°C along with other Items upon Approval from NUPCO/MOI. The Quarantined items must be blocked/quarantined in WMS system to avoid further allocation.

5.7.3 The controlled drug products which present risks of abuse should be stored in a dedicated area that is subject to appropriate strict safety and security measures.

5.7.4 Storage location(s) that are identified as "hot spot" during the temperature mapping of the warehouse, can only be stored with "non- temperature sensitive items". Signage/Label such as "Not for temperature sensitive items" are to be displayed on these locations at all times to caution staff for compliance. However the all Warehouse temperature shall be maintained +15°C to +25°C and Cold rooms at +2°C to +8°C, Freezer Room -1°C to -17°C.

5.7.5 Adequate precautions should be taken against spillage or breakage as per SOP SMSA-HC16.

5.7.6 There should be adequate lighting to enable all operations to be carried out accurately and safely.

5.7.7 The storage areas shall have appropriate ventilation.

5.7.8 Where controlled environmental storage conditions are required, these conditions should be continuously monitored and documented.

5.7.9 Appropriate actions, on the premises, equipment and/or materials should be taken when the storage conditions are not met. As far as possible, the actual storage temperature should be expressed quantitatively.

5.7.10 As the actual storage temperature is not expressed quantitatively or stated (in terms of range) on the labels of the registered product, hence the following Tables definitions should be used as a guidance where applicable:

5.7.11

On The Label:	Guidance Values:
Freezer	The temperature is thermostatically controlled between -1°C and -20°C.
Cold Room	The temperature is thermostatically controlled between 2°C and 8°C.
Cold Place	The temperature does not exceed 8°C.

Room Temperature	The temperature is between 15°C and 25°C.
Do not store over 30°C	The temperature is between 2°C and 30°C.
Do not store over 25°C	The temperature is between 2°C and 25°C.
Do not store over 15°C	The temperature is between 2°C and 15°C.
Do not store over 8°C	The temperature is between 2°C and 8°C.
Do not store below 8°C	The temperature is between 8°C and 25°C.

5.7.12 Where storage conditions stated on the label means the following:

ON THE LABEL	GUIDANCE VALUES
Protect from moisture	No more than 60% relative humidity in normal storage conditions; to be provided to the user in a moisture-resistant container
Protect from light	To be provided to the user in a light resistant container

5.7.13 Temperature of the storage areas must be measured at suitable predetermined intervals to show the maximum and minimum temperatures for the day and recorded. Where needed, humidity measurements shall also be performed.

5.7.14 The instruments used for measuring and monitoring temperature and humidity should be calibrated or verified for accuracy and the results of such calibrations or verifications should be recorded and retained.

5.7.15 The storage racks shall be checked for their condition.

5.7.16 There should be the adequate space of 1.5 meter between Roof and last level stored products on the top shelves.

5.7.17 Usage of PPEs mainly safety Helmet & safety shoes shall be enforced all the time.

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5.7.18 Manual Lifting instruction shall be followed as outlined in the Method statement document.

5.7.19 There shall be adequate clearance of pathways in storage area.

5.7.20 It shall be ensure that no emergency Doors and pathways are obstructed by any Material including temporary storage situations.

5.7.21 Fire extinguishers and fire hoses shall be mounted on elevated locations.

6.0 RECORD

Title of Record	Custodian	Retention Period
NA	NA	NA

7.0 Attachment/Reference

7.1 SMSA-HC16

8.0 DOCUMENT CHANGE RECORD

Rev No.	Effective Date	Nature of Change	Document Change Request No:
00	23-10-2016	New Document	NA
01	17-12-2017	Changes made in SOP as follows • Incorporated abbreviations in section3. • Incorporated new points 5.5 and 5.6 for heavy Pallets to be stored at lower shelves and staff shall wear PPEs for picking in height. • Amended the point 5.7.2 for the quarantine items in Cold room. • Amended the point 5.7.4 for the temperature range. • Amended the point 5.7.2 for the reference SOP SMSA-16 to be followed in case of spillage and obsoleted the sentence attacked by microorganism,	CR0191

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		contamination, and cross-contamination. • Amended the range for Room temperature to 15°C to 25°C.	
02		Changes made in SOP as follows • SOP Document ID amended as SMSA-HC unique ID format for all SOP. • Incorporated points 5.7.14 to 5.7.20 for health and Safety instructions.	

END OF DOCUMENT

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