	SMSA P.O. Box 63259 Riyadh 11526, K.S.A.		Document ID	SMSA-HC01
	STANDARD OPERATING PROCEDURE Mandatory Requirements		Revision no.	05
			Effective Date	01-06-2025
			Next Revision Date	31-05-2027
			Function	Warehouse
			Page	Page 1 of 7

1.0 PURPOSE

- 1.1 This procedure lays down the Warehouse mandatory requirement on Infrastructure, Cleanliness, and Storage of Products, Calibration of Equipment, Pest Control and Environmental safety conditions for operations in SMSA Warehouse.
- 1.2 The requirement for temperature and humidity controlled is to maintain product quality and to be strictly adhered to.

2.0 SCOPE


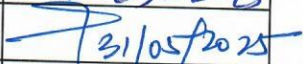

- 2.1 This procedure is applicable to all SMSA Employee working with pharmaceutical Warehouse.


3.0 ABBREVIATIONS/DEFINITION

No.	Term	Description
3.1	DMS	Data Logger Management System
3.2	°C	Degree Celsius
3.3	EHS	Environment Health and safety
3.4	SOP	Standard Operating Procedure
3.5	eg	example
3.6	AC	Air Conditioning

4.0 RESPONSIBILITY

- 4.1 The Warehouse Manager or pharmacist shall be responsible for the implementation and update for this procedure to fulfill operational and customer requirements.
- 4.2 The Utility Executive and Safety & Security staff shall be responsible for the monitoring and recording of the Temperature & Humidity records reading.
- 4.3 The Utility Executive shall also be responsible for monitoring and ensuring that the Pest Control Program is carried out as schedule.

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

	SMSA P.O. Box 63259 Riyadh 11526, K.S.A.	Document ID	SMSA-HC01
	STANDARD OPERATING PROCEDURE Mandatory Requirements	Revision no.	05
		Effective Date	01-06-2025
		Next Revision Date	31-05-2027
		Function	Warehouse
		Page	Page 2 of 7

- 4.4 The Warehouse Manager or pharmacist is responsible for maintaining the safe condition of personal and property and for ensuring the environmental requirements are met.

5.0 PROCEDURE

5.1 Monitoring of Temperature Control


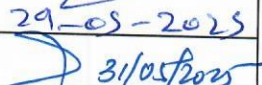
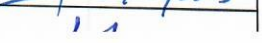
- 5.1.1 The air-conditioned warehouse is operating at temperature range 15°C to 25°C. Maximum and minimum temperatures are also recorded in DMS on daily basis. (Refer to SOP-HC 26)
- 5.1.2 Temperature value is to be recorded as well. Any reading exceed the specific range will be reported to Warehouse Supervisor who in turn will raise to the Admin Facility Supervisor on matters relating to power supply and air-conditioning.
- 5.1.3 The Admin Facility Supervisor will notify the contractor to carry out checks and rectification accordingly.


5.2 Warehouse Cleanliness

- 5.2.1 The Warehouse storage areas are to be kept clean, dry and free of accumulated waste and dust at all times.
- 5.2.2 Cleaning Program is drawn up for staff to perform the cleaning. The warehouse areas are to be cleaned accordance to the checklist on a monthly basis to keep and maintain its cleanliness (see attached checklist as per Annexure A).
- 5.2.3 Floor under the pallets racking are to be cleaned when the pallets are removed.

5.3 Storage of Products

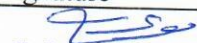

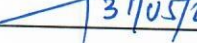
- 5.3.1 Items are to be stored in carton boxes on storage shelving. The product must be clearly identified on carton box with bar code label indicating the:
- 5.3.1.1 Product Number
 - 5.3.1.2 Description
 - 5.3.1.3 Lot Number
 - 5.3.1.4 Expiry date.
- 5.3.2 Items are stored on pallets to allow easy cleaning, inspection and retrieval. Pallets are to be well maintained and kept in good state of cleanliness.
- 5.3.3 Designated areas are identified to store different range of items. SMSA Warehouse work areas and layout are marked according to its work flow processes into Inbound, Outbound, Storage and Quarantine Area.
- 5.3.4 The following listed are Items that are to be segregated from serviceable stock and place under quarantine:


	Name & Designation	Signature
Author/ Originator of Doc Change	MOAYAD MOHAMEDAW PHARMACIST	
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	SMSA P.O. Box 63259 Riyadh 11526, K.S.A.	Document ID	SMSA-HC01
	STANDARD OPERATING PROCEDURE Mandatory Requirements	Revision no.	05
		Effective Date	01-06-2025
		Next Revision Date	31-05-2027
		Function	Warehouse
		Page	Page 3 of 7

- 5.3.4.1 expired
- 5.3.4.2 rejected/ damaged
- 5.3.4.3 recalled
- 5.3.4.4 returned
- 5.3.4.5 condemned items
- 5.3.4.6 counterfeit items
- 5.3.5 Storage method of quarantine items are identified as follows:
- 5.3.5.1 Quarantine items are to be kept at the designated rack under lock & key and label 'Quarantine' with reason of quarantine to be clearly marked on the product.
- 5.3.5.2 Cold Chain Items: To be quarantined at desired temperature with indication 'Quarantine' inside the Cold Room or in general quarantine area if approved from NUPCO.
- 5.3.6 Products required special storage conditions e.g. Control Drug are identified and stored under lock and key.
- 5.3.7 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 such as "Not for temperature sensitive items" are to be displayed on these locations at all times to caution staff for compliance.
- 5.3.8 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 definitions should be used as a guidance where applicable :
- 5.3.9

On The Label:	Guidance Values:
1) Freezer	The temperature is thermostatically controlled between -1°C to -17°C
2) Refrigerator/(cold Room)	The temperature is thermostatically controlled between 2°C and 8°C.
3) Cold Place	The temperature does not exceed 8°C.
4) Cool Place	The temperature is between 8°C and 15°C.
5) Room Temperature	The temperature is between 15°C and 25°C
6) Warm	The temperature is between 30°C and 40°C.
7) Excessive Heat	The temperature is above 40°C.
8) Do not store over 30°C	The temperature is between 2°C and 30°C.
9) Do not store over 25°C	The temperature is between 2°C and 25°C.
10) Do not store over 15°C	The temperature is between 2°C and 15°C.
11) Do not store over 8°C	The temperature is between 2°C and 8°C.
12) Do not store below 8°C	The temperature is between 8°C and 25°C.

	Name & Designation	Signature
Author/ Originator of Doc Change	MOAYAD MOHAMEDAW PHARMACUT	 29-05-2025
Reviewer (Process Owner)	M. J. M. Jaceel Warehouse Supervisor	 31/05/2025
Approving Authority	Jagat Singh	

	SMSA P.O. Box 63259 Riyadh 11526, K.S.A.		Document ID	SMSA-HC01
	STANDARD OPERATING PROCEDURE Mandatory Requirements		Revision no.	05
			Effective Date	01-06-2025
			Next Revision Date	31-05-2027
			Function	Warehouse
			Page	Page 4 of 7

5.4 Calibration for Equipment:


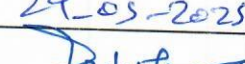
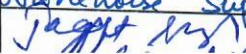
- 5.4.1 The temperature monitoring devices and equipment are scheduled for yearly calibration, scheduled by the Project Manager.
- 5.4.2 All temperature device / equipment that are calibrated should be tagged with calibrated labels updated with calibrated date and date due for next calibration.
- 5.4.3 Any new temperature device prior to installation will be calibrated.
- 5.4.4 The temperature devices should be calibrated based on a 3-point calibration within the temperature range of the device's operating temperature environment. E.g. For temperature range of 2 to 8 °C, the device should be calibrated at 2, 4 and 8 °C.


5.5 Pest Control

- 5.5.1 Pest control program is scheduled by Project Manager and Contractor will carry out monthly inspection per recommended location.
- 5.5.2 Pest control checklist and report will be submitted by Contractor upon completion of inspection to Warehouse Supervisor.
- 5.5.3 Report on area of concern for improvement, if any, will be followed up for necessary rectification.

5.6 EHS Conditions

- 5.6.1 Ensure that fire monitoring alarm system and firefighting system are in place and functional at all the time. This includes and ensures that major fire components are available and are of adequate numbers, also they maintained and inspected quarterly or frequently/semiannually.
- 5.6.2 The safety conditions needed for the protection of employee and visitors' health and safety are to be ensured through the introduction of safety control measures, awareness and inspections. Similarly, the safety control measures to preserve the property, material and continuity of work shall also be observed.
- 5.6.3 Environmental control measures including proper waste management, recycling, energy and water conservation and prevention of pollution to the environment shall be in place.
- 5.6.4 All gases used or replaced in Chillers/ AC shall be environmentally friendly.

	Name & Designation	Signature
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	SMSA P.O. Box 63259 Riyadh 11526, K.S.A.	Document ID	SMSA-HC01
	STANDARD OPERATING PROCEDURE Mandatory Requirements	Revision no.	05
		Effective Date	01-06-2025
		Next Revision Date	31-05-2027
		Function	Warehouse
		Page	Page 5 of 7

6.0 RECORD

Title of Record	Custodian	Retention Period
Warehouse Temperature Record	Utility Executive	5 years
Calibration / Maintenance Report	Utility Executive	5 years
Housekeeping Record	Storage Team Leader	3 Years
Pest Control Report	Utility Executive	5 Years


7.0 Attachment/Reference

7.1 Annexure A – Monthly Cleaning Checklist.

8.0 DOCUMENT CHANGE RECORD


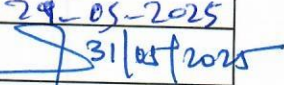

Rev No.	Effective Date	Nature of Change	Document Change Request No.
00	11-05-2016	New document	NA
01	31-01-2018	Changes Made in the SOP as follows <ul style="list-style-type: none"> SOP Format updated to uniform all SOPs. SOP Document ID amended as SMSA-HC unique ID format for all SOP. Point 1.1 amended by adding Environmental safety conditions Incorporated point 2 for the scope of the SOP Incorporated point 3 for abbreviations used in SOP Amended the point 4.1, 4.2 & 4.3 by adding the responsibilities of Manger and assistant project manager. Incorporated point 4.4 for the responsibilities for EHS. Amended the point 5.1 by correcting the temperature values and recording from DMS. Amended the point 5.3.5.2 by adding the quarantine area in Cold room. Amended the table under point 5.3.8 for 	


	Name & Designation	Signature
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Reviewer (Process Owner)	PHARMACUT M. J. M. J. J. J.	29-05-2025
Approving Authority	Warehouse Supervisor Jagat	31/05/2025

	SMSA P.O. Box 63259 Riyadh 11526, K.S.A.	Document ID	SMSA-HC01
	STANDARD OPERATING PROCEDURE Mandatory Requirements	Revision no.	05
		Effective Date	01-05-2025
		Next Revision Date	31-05-2027
		Function	Warehouse
		Page	Page 6 of 7

12-01-2022	<p>Freezer and room temperature by adding correct values of temperature for Freezer and room temperature.</p> <ul style="list-style-type: none"> • Incorporated the point 5.6 for EHS conditions. • Amended the section 6. For records by adding the custodian Utility executive as actual. • Point 5.1.1 removed (if any break down in DMS then Annexure A shall be filled out daily twice as a record). Added (Refer to SOP-HC 26) • Point 5.1.2 removed (Relative Humidity) • Point 5.1.4 Removed. • Point 7.1 adjusted Annexure A Monthly Cleaning Checklist • Point 7.2 Removed. • Point 7.3 Removed 	
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END OF THE DOCUMENT

	Name & Designation	Signature
Author/ Originator of Doc Change	MOTYAD MOHAMEDAW PHARMACIST	
Reviewer (Process Owner)	M.S.M. Jameel Warehouse Supervisor	29-05-2025 
Approving Authority	Taghi Hussien	

	SMSA P.O. Box 63259 Riyadh 11526, K.S.A.	Document ID	SMSA-HC01
	STANDARD OPERATING PROCEDURE Mandatory Requirements	Revision no.	05
		Effective Date	01-06-2025
		Next Revision Date	31-05-2027
		Function	Warehouse
		Page	Page 7 of 7



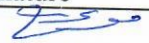


Monthly Cleaning Checklist

Annex A

AREA	Date	Name	Sign	Remarks

Checked by _____

Approved by _____

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



Monthly Cleaning Checklist

Annex A

AREA	Date	Name	Sign	Remarks

Checked by _____

Approved by _____