EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the site	**المخزن الأقليمي للطعوم والأمصال - مديريه الشئون الصحية بمحافظه مرسي مطروح**
Inspected site	
Address of inspected site	**ديوان المديرية شارع شكري القويتلي بجوار المطافي – محافظه مطروح**
Inspection details	
Dates of inspection	**26\1\2026**
Type of inspection	Local, planned, and announced inspection.
Scope	
Scope	This is a routine inspection conducted over the warehouse within the execution of annual inspection plan. The scope is covering general GSDP items of QMS, QRM, Management review, personnel, premises and equipment, documentation, outsourced activities, complaints, returned goods, product recalls, and self-inspection, Stock control and rotation, qualification and validation, activities and operations, substandard and falsified product
General information about the site	
General information about the site	The warehouse is working in the storage& distribution of medical products that located in Matrouh City, Marsa Matrouh governorate.
Assessment of the Site Master File (SMF) if present	There was SMF it was reviewed and found complying with the guideline for drafting site master file; Annex 14, WHO Technical Report Series, No.961, 2011.
Abbreviations	
EDA GSDP WHO BPI CAPA SOPs	Egyptian Drug Authority Good Storage and Distribution Practice World Health Organization Biological Products Inspection Administration Corrective and Preventive Action

QMS QRM	Standard Operating Procedures Quality Management System Quality Risk Management
Part 2	**Brief summary of the findings and comments**
1. Quality management system (QMS)	The roles and responsibilities of personnel were clearly defined and understood by all individuals involved quality policy, the quality manual SOP. These were documented through written job descriptions, the SOP. There was an authorized organizational chart in place to indicate the responsibilities and interrelationships of personnel within the organization Documents that were reviewed and found accepted.
2. Quality risk management (QRM)	The company conducts Quality Risk Management (QRM) based on an established risk management procedure SOP was reviewed and found accepted. This procedure outlined the process for assessing, controlling, communicating, and reviewing risks at every stage of the supply chain. There were risk mitigation controls monitoring. - Risk assessment for storing of products in the refrigerators and freezers was reviewed and found accepted.
3. Management Review	The management review SOP. involved senior management and focuses on reviewing the overall effectiveness of the quality system. was reviewed and found accepted, last minutes coded was reviewed and found accepted.
4. Complaints	Complaints are handled according to SOP reviewed and found accepted as it ensures proper investigation and corrective actions are taken if needed. Each complaint is evaluated to determine if it could indicate a wider issue affecting multiple batches of the product. -Log book was reviewed and found accepted.
5. Returned goods.	SOP were in place for handling returned products it was reviewed and found accepted. These procedures ensured that returned goods were assessed for quality issues and stored in a secure location

	while decisions are made regarding their further use or destruction. -SOP was reviewed and found accepted. -Log book for returned product was reviewed and found accepted. -Report for returned product was reviewed and found accepted.
6. Recalls	SOP included notifying regulatory authorities and all relevant stakeholders in the event of a recall. The process ensured that products were recalled efficiently and that communication was clear throughout the process. -Log book for recalled product -There was mock recall was performed successfully and the results shows that the recall system was effective and capable of ensuring product traceability. -Log book for mock recall and Distribution list were reviewed and found accepted.
7. Self-inspection	SOP was reviewed and found accepted. Internal audits were conducted according to the company's procedures to ensure compliance with quality standards. -Self-inspections plan Self-inspections team auditor and final self-inspections report were reviewed and found accepted.
8. Premises	Premises were suitably located, designed, constructed and maintained, to ensure appropriate operations such as storage, cleaning, and picking of medical products. - There was a sufficient security provided and access controlled with SOP was reviewed and found accepted. -There was a suitable air conditioning system to ensure proper storage conditions in the warehouse. -Temperature were controlled and monitored at regular intervals and recorded, fire extinguishers were in place and pest traps and insect killers. - The cold room store was present but out of use, products were stored in the refrigerators.
9. Stock control and rotation	Written procedures for stock control and product rotation were in

	place with SOP, was reviewed and found accepted, it ensures that products stock levels were controlled. -Report was reviewed and found accepted. -The last stock control and rotation was conducted successfully and properly documented.
10. Equipment	Equipment used with appropriate design. The list was reviewed and found accepted. The list of equipment suitably located for its intended use and it was properly maintained. Equipment, including computerized systems (UPA), found suitable for its intended use The identified deficiency was addressed following the submitted CAPA
11. Qualification and validation	-Qualification and validation had SOP was reviewed and found accepted. The identified deficiency was addressed following the submitted CAPA
12. Personnel	The company employs a sufficient number of qualified personnel to carry out all necessary activities. Training SOP. It provided to ensure that staff are equipped with the necessary knowledge and skills to perform their duties. - Appropriate procedures cover health hygiene and the clothing of personnel and safety procedures for personnel coded, was reviewed and accepted. -Training plan and Training on good storage and distribution of product with attendance sheet and evaluation report were reviewed and accepted.
13. Documentation	Documentation SOPs are well-structured, with written procedures in place for all major activities. Records, including temperature and humidity logs, are maintained to ensure compliance with storage requirements. Document control is handled according to established procedures, ensuring that documents are reviewed and updated regularly.
14. Activities and operation	-All key activities, including receiving SOP with record sheet reviewed and accepted.

	-Storage of product in cold room SOP, Storage of product in refrigerators and Storage of product in fridges SOP were reviewed and accepted. There was appropriate control to prevent and handle spillage and breakage with SOP was reviewed and accepted. -Dispatching the product with SOP with record sheet. Distribution of products SOP were reviewed and found accepted. -List of drivers, Recorded sheet for temperature monitoring during transportation were reviewed and found accepted. - Temperature were controlled and monitored at regular intervals and recorded according to SOP, record sheet it was reviewed and found accepted -There was a written procedure for fire control including prevention of fire, fire detection SOP was reviewed and found accepted. -There was a pest control program in place with SOP, procedures for cleaning SOP, were reviewed and found accepted.
15. Outsourced activities	All activity relating to the storage and distribution of a medical product that is delegated to another person or entity performed by the appropriately authorized parties, in accordance with national legislation and the terms of a written contract, with SOP was reviewed and found accepted.
16. Substandard and falsified products	The company has SOP in place for handling of product these procedures outline steps for identifying and segregating such products to prevent them from being distributed with recorded log book. It was reviewed and found accepted.
Part 3	**Inspection outcome**

- Based on the areas inspected, the people met, and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, (**المخزن الأقليمي للمطعوم والأمصال - مديريه الشئون الصحية بمحافظه مرسي مطروح**) Located at (ديوان المديرية شارع شكري القويتلي بجوار المطافي – محافظه مطروح), was considered to be operating at an **(acceptable)** level in compliance

with WHO GSDP standards as adopted by EDA. • All the non-compliances observed during the inspection that were listed in the full report as well as those reflected in the EDA-PIR, were addressed by warehouse, to a satisfactory level, prior to the publication of the EDA-PIR • This EDA-PIR will remain valid for till next inspection up to three years, as long as there is any warning or recall from SRA.	
Part 4	**List of GSDP Guidelines referenced in the inspection report**
	• Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9. Short name: WHO TRS No. 961, Annex 9 https://www.who.int/publications/m/item/trs961-Annex9-modelguidanceforstoragetransport • Good storage and distribution practices for medical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifty-Fourth Report. Geneva, World Health Organization, 2020 (WHO Technical Report Series, No. 1025), Annex 7. Short name: WHO TRS No. 1025, Annex 7. https://www.who.int/publications/m/item/trs-1025-annex-7 short name: WHO TRS No. 1025, Annex 7 • WHO guidelines for drafting a site master file World Health Organization, Expert Committee on Specifications for Pharmaceutical Preparations. 2011 (WHO Technical Report Series, No. 961), Annex 14. https://www.who.int/publications/m/item/trs961-annex14 Short name: WHO TRS 961 - Annex 14