EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the site	المخزن الإقليمي للطعوم والأمصال - مديريه الشئون الصحيه بمحافظه جنوب سيناء
Inspected site	
Address of inspected site	ديوان المديرية شارع طابا - طور سيناء – مدينه الطور – محافظه جنوب سيناء
Inspection details	
Dates of inspection	**22\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 ELTOOR City, South Sinai governorate.
Assessment of the Site Master File (SMF) if present	**SMF** was 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	Egyptian Drug Authority Good Storage and Distribution Practice World Health Organization Biological Products Inspection Administration Corrective and Preventive Action

SOPs 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 was reviewed. These were documented through written job description. There was an authorized organizational chart in place to indicate the responsibilities and interrelationships of personnel within the organization. This chart helps ensure that each person's duties are clearly understood and aligns with the quality objectives of the company. Documents 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 .This procedure outlined the process for assessing, controlling, communicating, and reviewing risks at every stage of the supply chain. Documents were reviewed and found accepted. - Risk study for storing of products in the refrigerators and freezers were reviewed and found accepted.
3. Management Review	The management review SOP was reviewed involved senior management and focuses on reviewing the overall effectiveness of the quality system, regarding to management review; The identified deficiency was addressed following the submitted CAPA.
4. Complaints	Complaints are handled according to SOP. That ensure 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. Documents were reviewed and found accepted.
5. Returned goods.	SOP were in place for handling returned products. 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.
6. Recalls	SOP was reviewed and found accepted as 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. - There was mock recall was performed successfully and the results shows that the recall system was effective and capable of ensuring product traceability. was reviewed and found accepted.
7. Self-inspection	SOP was reviewed. Internal audits were conducted according to the company's procedures to ensure compliance with quality standards, self-inspection was conducted on the branch on time, its report was reviewed The identified deficiency was addressed following the submitted CAPA.
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. -There was a suitable air conditioning system to ensure proper storage conditions in the warehouse. Temperature was controlled and monitored at regular intervals and recorded.
9. Stock control and rotation	Written procedures for stock control and product rotation were in place with SOP, to ensure that products are stored properly and used before their expiration dates according to FEFO rules. This system helps maintain product quality by ensuring that older stock is used before newer stock. Documents were reviewed and found accepted.
10. Equipment	Equipment used with appropriate design. The list of equipment suitably located and it was properly maintained, SOP for calibration. Equipment, including computerized systems, found suitable for its intended use
11. Qualification and validation	Qualification and validation had SOP was reviewed. -Thermal mapping study executed for cold room store with report was reviewed. 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 was reviewed. Is 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 was reviewed and accepted. Training about GSDP guidelines implementation conducted on time, was reviewed and accepted. The identified deficiency was addressed by the warehouse in the submitted CAPA.
13. Documentation	Documentation SOP was reviewed and found accepted as documents were well-structured, Document control was handled according to established procedures, ensuring that documents were reviewed and updated regularly.
14. Activities and operation	-All key activities, including receiving SOP with record sheet were reviewed and found accepted. -Storage of product in cold room SOP, Storage of product in refrigerators SOP, Storage of product in fridges SOP were reviewed and found accepted. There was appropriate control to prevent and handle spillage and breakage with SOP were reviewed and found accepted. Distribution of products SOP and list of drivers. Were reviewed and found accepted. -Recorded sheet for temperature monitoring during transportation were reviewed and found accepted. -There was a written procedure for fire control including prevention of fire, fire detection SOP. There was a pest control program in place with SOP Procedures for cleaning SOP Documents 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	The company has SOP in place for handling of counterfeit product

products	SOP 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 الإقليمي للطعوم والأمصال - مديريه الشئون الصحيه بمحافظه جنوب سيناء) Located at (ديوان المديرية شارع طابا - طور سيناء – مدينه الطور – محافظه جنوب سيناء), 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 the 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