EDA Public Inspection Report (GSDP)

Part 1	General information
Inspected site details	
warehouse information	
Name of the site	مخازن الطعوم والامصال مديرية الشؤن الصحية بني سويف
Inspected site	
Address of inspected site	بندر بني سويف –شارع سعد زغلول ديوان عام مديرية الصحة
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 distribution of vaccines with no hazardous and narcotic stored in the site. No other activities are done by the warehouse regarding the importation or packaging of medical products.
Assessment of the Site Master File (SMF) if present	Site Master File was reviewed and found comply with the guideline for drafting site master file; Annex 14, WHO Technical Report Series, No.961, 2011.
Abbreviations	
EDA GSDP WHO BPI CAPA SOPs QMS	Egyptian Drug Authority Good Storage and Distribution Practice World Health Organization Biological Products Inspection Administration Corrective and Preventive Action Standard Operating Procedures Quality Management System

QRM	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. These were documented through written job descriptions quality manual coded and there was an authorized organizational chart in place to indicate the responsibilities and interrelationships of personnel within the organization coded. 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. This procedure outlines the process for controlling, communicating, and reviewing risks at every stage of the supply chain. The system allows for the identification of potential risks that may impact the quality of products, and appropriate control measures are developed and implemented to address these risks. The effectiveness of these controls is periodically evaluated to ensure they continue to mitigate risks effectively. SOP for QRM was reviewed and found accepted. -Risk assessment of storing products in refrigerator was reviewed and found accepted.
3. Management Review	There was a system for periodic management according to procedure for management review was reviewed and found accepted, the management review process involves senior management and focuses on reviewing the overall effectiveness of the quality system. This is done using quality metrics and key performance indicators (KPIs). The review process also identifies areas for continual improvement and ensures that follow-up actions are taken based on recommendations from previous management review, Last Management Review meeting was held on time and was reviewed and found accepted.
4. Complaints	Complaints were handled according to established procedures 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. Handling of Products and customer service complaints SOP was

	reviewed and found accepted.
5. Returned goods.	Written procedures are in place for handling returned products. These procedures ensure that returned goods were assessed for quality issues and stored in a secure location while decisions were made regarding their further use or destruction. There was records to destruction of expired products was reviewed and found accepted.
6. Recalls	A comprehensive system for handling product recalls is in place. This system includes notifying regulatory authorities and all relevant stakeholders in the event of a recall. The process ensures that products are recalled efficiently and that communication is clear throughout the process. The company had in place a system for promptly managing recalls in accordance with procedure, last Mock Recall was performed successfully and the results shows that the recall system was effective and capable of ensuring product traceability.
7. Self-inspection	Internal audits, or self-inspections, are conducted according to the company's procedures to ensure compliance with quality standards. These audits help identify areas for improvement and ensure that all quality-related activities are in line with regulatory requirements. Corrective actions are taken based on the results of these audits. Last inspection Report were reviewed and found accepted.
8. Premises	The company's premises include separated areas for receiving and dispatching goods by time. The storage area is secured with access controls (list of employees) to prevent unauthorized entry. The facility is equipped with fire control systems, including fire detection and firefighting equipment. In addition, a rodent and pest control program are in place to ensure cleanliness and product safety. The identified deficiency was resolved following the implementation of the submitted CAPA
9. Stock control and rotation	Written procedures for stock control and product rotation are in place to ensure that products are stored properly and used before their expiration dates. This system helps maintain product quality by ensuring that older stock is used before newer stock. SOP for stock control and rotation was reviewed and found accepted.
10. Equipment	Equipment used with appropriate design, and suitably located for its intended use and it was properly maintained.

	SOP for equipment was reviewed and found accepted.
11. Qualification and validation	SOP for Qualification and validation was reviewed Thermal Mapping for cold room code in winter was performed protocol and report reviewed and found comply The identified deficiency was addressed in the warehouse submitted CAPA.
12. Personnel	The company employs a sufficient number of qualified personnel to carry out all necessary activities. Training is provided to ensure that staff were equipped with the necessary knowledge and skills to perform their duties. Procedures for training was reviewed and initial, continued and on job training were conducted SOP for personal Hygiene was reviewed and found accepted. Last training about GSDP was reviewed and found accepted.
13. Documentation	Documentation practices 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. In general, documents were regularly reviewed and Procedure for good documentation practices was reviewed and found accepted.
14. Activities and operation	**14.1 Receipt and dispatch** Activities relating to receiving processes were carried out according to Procedure, SOP for Receipt, SOP for Picking and Dispatch SOP was reviewed and found accepted. **14.2 Storage** Activities relating to storage processes, all medical products requiring specific storage conditions stored in accordance with their requirements, SOP for freezed, vaccine SOP for cooling system, SOP for Storage in refrigerators ,SOP for broken products, SOP for Deviation, SOP for change control and SOP for Temperature recording were reviewed and found accepted. **14.3.Distribution and transport** SOP for Distribution and Transportation was reviewed and found accepted
15. Outsourced activities	If any activity relating to the storage and distribution of a medical product delegated to another person or entity it performed by the appropriately authorized parties, in accordance with national legislation and the terms of a written contract. SOP was reviewed and found accepted.

16. Substandard and falsified products	Handling the substandard and falsified products was according the 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, (مخازن الطعوم والامصال مديرية الشؤن الصحية بني سويف) Located at (شارع سعد زغلول ديوان عام مديرية الصحة –بندر بني سويف) 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**
	• 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 • 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