EDA Public Inspection Report (GSDP)

Part 1	General information
Inspected site details	
warehouse information	
Name of the site	مخزن الطعوم والأمصال - مديرية الشئون الصحية بكفرالشيخ
Inspected site	
Address of inspected site	Al-Estad Street – General Administration of Pharmacy Building – Kafr El-Sheikh شارع الأستاد – مبنى الأدارة العامة للصيدلة- كفرالشيخ
Inspection details	
Dates of inspection	26-01-2026
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 medical products, no raw material, hazardous or narcotic stored in the site.
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 Standard Operating Procedures

QMS QRM	Quality Management System Quality Risk Management
Part 2	**Brief summary of the findings and comments**
1. Quality management system (QMS)	There was SOP The roles and responsibilities of personnel were defined and understood by all individuals involved which were documented as written job descriptions. There was Written SOP for jobs descriptions there was an authorized organizational chart in place to indicate the responsibilities and interrelationships of personnel within the organization.
2. Quality risk management (QRM)	The warehouse conducted Quality Risk Management (QRM) process according to the established risk management procedure .This procedure outlined the process for controlling, communicating, and reviewing risks at every stage of the supply chain. There was Risk assessment for storing of products in the refrigerators and freezers was reviewed and found accepted.
3. Management Review	The SOP was presented by the warehouse, management review process involved senior management and focused on reviewing the overall effectiveness of the quality system. The review process also identified areas for continual improvement and ensured that follow-up actions were taken based on recommendations from previous management reviews. The SOP was reviewed and found accepted.
4. Complaints	Complaints were handled according to established procedures that ensured proper investigation and corrective actions were taken if needed. It was reviewed and found accepted.
5. Returned goods.	Written procedures were in place for handling returned products. These procedures ensure that returned goods were assessed for quality issues and stored in a secured location while decisions were made regarding their further use or destruction. The SOP was reviewed and found accepted.
6. Recalls	Written procedures were in place for handling recalled products was reviewed and found accepted. The process ensured that products were recalled efficiently throughout the process, mock recall was done annually, 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	Procedure for self -inspection was reviewed and there was periodic self-inspection conducted and the last audit performance, the self-inspection team should be trained and certified. The last self-inspection was performed its report was reviewed and found accepted.
8. Premises	The warehouse had adequate space for storage, it was clean and was well-designed and maintained. Premises were protected against entry of birds and other animals there was two air curtains, two mosquito and insect zappers, and four mouse traps. There was two air condition, receiving and dispatch bays were separated to avoid mix-up.
9. Stock control and rotation	Written procedures were in place for stock reconciliation. In case of a discrepancy in quantities, whether a shortage or surplus, the warehouse management will trace the item's movement to determine the root cause. An investigation will be conducted into the inventory results to identify the primary reason and implement corrective and preventative measures to avoid recurrence.
10. Equipment	SOP for maintenance was in place and reviewed and found accepted. Firefighting equipment were available and served regularly The identified deficiency was addressed by the warehouse in the submitted CAPA.
11. Qualification and validation	Written procedures were in place for computer system (UPA) validation Written procedures were in place for qualification and validation. thermal mapping for the cold room was reviewed, The identified deficiency was resolved following the implementation of the submitted CAPA.
12. Personnel	Written procedures were in place for training Written procedures were in place for Personal hygiene. Written procedures were in place for safety sufficient number of qualified personnel was available to carry out all necessary activities. Training conducted on GSDP requirement was conducted on time, records were reviewed and found accepted.

13. Documentation	There was written SOP and Written SOP for SOP of SOPS Documentation system was well-structured and maintained. The SOP was reviewed and found accepted.
14. Activities and operation	There was written SOP for operations and activities receiving, storage, dispensing, transporting, and handling vaccines and serums SOP, storage in cold room, SOP storage in refrigerators Written SOP for storage in deep freezer SOP, SOP for handling light- and heat-sensitive preparations Written SOP for Transportation, and Ensuring the safe transport of vaccine shipments to central vaccine and serum warehouses SOP .All SOPs were reviewed and found accepted. These processes were managed in compliance with warehouse policies to ensure product quality was maintained throughout the supply chain.
15. Outsourced activities	There was written SOP for outsourced activities was reviewed and found accepted. There was no activity relating to the storage and distribution of a medical product that was delegated to another person or entity.
16. Substandard and falsified products	Written procedures were in place for Substandard and Falsified products. 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, (مخزن الطعوم والأمصال - مديرية الشئون الصحية بكفرالشيخ) Located at (Al-Estad Street – General Administration of Pharmacy Building – Kafr El-Sheikh شارع الأستاد – مبنى الأدارة العامة للصيدلة- كفرالشيخ), 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. short name: WHO TRS No. 1025, Annex 7 **https://www.who.int/publications/m/item/trs-1025-annex-7**