EDA Public Inspection Report (GSDP)

Part 1	General information
Inspected site details	
warehouse information	
Name of the site	مخزن الطعوم والأمصال - مديرية الشئون الصحية بالجيزة
Inspected site	
Address of inspected site	الإدارة الصحية بالشيخ زايد -الحي الحادي عشر -المجاورة الاولي -الجيزة
Inspection details	
Dates of inspection	28-01-2026
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 documented with form 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	Egyptian Drug Authority
GSDP	Good Storage and Distribution Practice
WHO	World Health Organization
BPI	Biological Products Inspection Administration
CAPA	Corrective and Preventive Action
SOPs	Standard Operating Procedures
QMS	Quality Management System
QRM	Quality Risk Management

Part 2	Brief summary of the findings and comments
1. Quality management system (QMS)	There was designed and documented QMS that was one of the ultimate responsibilities of senior management. roles and responsibilities of personnel were clearly defined and understood by all individuals involved. There were written procedures for all activities carried out through supply chain. The QMS was ensured through written SOP .there was an organizational chart was in place, documented with form to indicate the responsibilities and interrelationships of personnel within the organization, this chart helps to ensure that each person's duties were clearly understood and aligned with the quality objectives of the company. There were written job descriptions established in accordance with SOP, that clearly defined roles and responsibilities. Documents were reviewed and found to be accepted
2. Quality risk management (QRM)	The warehouse conducted (QRM) based on an established risk management procedure SOP, This procedure outlined the process for controlling, communicating, and reviewing risks at every stage of the supply chain. There was risk about separation between the receiving and delivery areas was reviewed and found accepted.
3. Management Review	There was written SOP.The management review process involves 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 should be taken based on recommendations from previous management reviews. The minutes of the latest management review meeting was held on time and was available Documents were reviewed and found to be accepted.
4. Complaints	SOP was in place. Complaints were handled according to established procedures that ensured proper investigation and corrective actions were taken if needed. Documents were reviewed and found to be accepted.
5. Returned goods.	Written procedures were in place for handling returned products SOP. These procedures ensure that returned goods were assessed Written procedures were in place for handling recalled products. The procedure ensured that products were recalled efficiently clear and appropriate storage conditions and communication with EDA

	were considered. There were secured and segregated area for recalled products. Distribution records were readily accessible for review. A recall was conducted for a product. Documents were reviewed and found to be accepted. for quality issues and stored in a secured location while decisions were made regarding their further use or destruction. There was SOP for handling rejected products. Documents were reviewed and found to be accepted
6. Recalls	Written procedures were in place for handling recalled products. The process ensured that products were recalled efficiently throughout the process. Distribution records were readily accessible for review. There was mock recall was performed successfully and the results shows that the recall system was effective and capable of ensuring product traceability. Documents were reviewed and found to be accepted.
7. Self-inspection	Written procedures were in place for self-inspection to ensure that the team of self-inspection should be competent, independent and should have appropriate knowledge and experience, appropriate CAPAs should be taken and records should be kept for a defined period Documents were reviewed and found to be accepted.
8. Premises	Premises were suitably located, designed, constructed and maintained to ensure appropriate operations. Sufficient lighting and ventilation to ensure required segregation, appropriate storage conditions, sufficient security. There were a cold room and two freezers to control storage conditions for products to be stored under controlled temperature. Products were stored off the floor. Receiving and dispatching activities were time separated. Temperature was controlled, monitored using monitors and recorded at regular intervals. Rodent traps, insect light traps, and fire extinguishers were available and serviced regularly. Documents were reviewed and found to be accepted The identified deficiency was addressed following the implementation of the submitted CAPA.
9. Stock control and rotation	Written procedure for physical inventory, was in place to ensure that periodic stock reconciliation should be performed at defined intervals and products should be stored properly and used before their expiration dates as the “first expired first out “rule should be

	followed. Documents were reviewed and found to be accepted.
10. Equipment	Written SOP was available and SOP for maintenance were in place. All equipment used were appropriately designed, and suitably located for its intended use and it was properly maintained. Fire extinguishers, insect trap, cold room, and two freezers. Were available. Official computerized system was available and capable of achieving the desired outputs and results The identified deficiency was addressed following the implementation of 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. There was a cold room with fridge tag thermometer, two deep freezers each one had fridge tag thermometer. There was documents were reviewed and found to be accepted The identified deficiency was addressed 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 was provided to ensure that staff were equipped with the necessary knowledge and skills to perform their duties. Records of training on GSDP performed and were available. Documents were reviewed and found to be accepted.
13. Documentation	There was written SOP, and Written SOP for SOP of SOPS Documentation system was well-structure The identified deficiency was addressed following the implementation of the submitted CAPA.
14. Activities and operation	Medical products were supplied from appropriately authorized suppliers and deliveries were examined for damage, and completeness of the order at the time of receiving. warehouse was following FEFO arrangement and products were stored. dispatched, transported and distributed in accordance with their requirements. Vehicles used were adequately equipped and designed. There were written SOPs for operations and activities receiving,

	storage, dispensing, transporting, and handling vaccines and serums, storage in cold room .SOP for storage in refrigerators, Written SOP for storage in deep freezer 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. Documents were reviewed and found to be accepted.
15. Outsourced activities	There was written SOP for outsourced activities. There was no activity relating to the storage and distribution of a medical product that was delegated to another person or entity. Documents were reviewed and found to be accepted
16. Substandard and falsified products	Written procedures were in place for Substandard and Falsified products. Was reviewed and found to be 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 الإدارة الصحية بالشيخ زايد -الحي الحادي عشر -) Located at (الطعوم والأمصال - مديرية الشئون الصحية بالجيزة -المجاورة الاولي -الجيزة), 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