EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the site	**مخازن طعوم مديريات الشئون الصحية - القاهرة**
Inspected site	
Address of inspected	مستشفى الحميات امتداد شارع رمسيس -القاهرة
Inspection details	
Dates of inspection	28/1/2026
Type of inspection	***local, planned, and announced***
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. 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	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 QMS QRM	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 Quality Risk Management
Part 2	**Brief summary of the findings and comments**
1. Quality management system (QMS)	The QMS was ensured through written quality manual .There was organizational chart in place to indicate the responsibilities and

	interrelationships of personnel within the organization There was job description that helps ensure that each person's duties are clearly understood and aligns with the quality objectives of the warehouse. Job description was reviewed and found that it clearly define roles, responsibilities & qualifications needed.
2. Quality risk management (QRM)	QRM was conducted based on SOP it was signed and dated by QA manager. It was reviewed and there was a system to assess, control, communicate and review risks identified at all stages in the supply chain to address all risks using failure mode and effect analysis (FMEA) tool. Risk assessment reports were 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. Documents were reviewed and found Accepted. Last meeting was on time. They were reviewed and found accepted.
4. Complaints	Handling of customer complaint SOP was reviewed and found accepted as there was classification for the incoming complaints to (critical-major-minor). Each complaint is evaluated to determine if it could indicate a wider issue affecting multiple batches of the product.
5. Returned goods.	Handling of returned goods SOP are in place. These procedures ensure that returned goods are assessed for quality issues and stored in a secure location while decisions are made regarding their further use or not. Also SOP for rejected products was reviewed and found accepted.
6. Recalls	There was written procedure for recall. There was secured, segregated area for recalled products. Communication with the EDA was found in the recall SOP. There was mock recall was performed successfully and the results shows that the recall system was effective and capable of ensuring product traceability They were reviewed and found accepted.
7. Self-inspection	There was SOP for self -inspection. There was periodic self-inspection conducted according to annual plan. The team conducting the inspection was independent and competent. Records of self-inspection were reviewed and last self-inspection report They were reviewed and found accepted.
8. Premises	Premises were suitably located, designed, constructed and maintained to ensure appropriate operations. Sufficient lighting and ventilation to ensure required appropriate storage conditions and cleanliness. There was air conditioning system. There was sufficient

	security. Receiving and dispatch activities were separated. There was allocation system.
9. Stock control and rotation	Written procedures were in place for stock control and rotation, SOP to ensure that products were stored properly and used before their expiration dates as (first expired first out) rule was followed. Periodic stock reconciliation performed at defined intervals by comparing the actual and recorded stock. The last stock control and rotation was conducted successfully and properly documented
10. Equipment	Equipment used appropriately designed, and suitably located for its intended use and it was properly maintained. Temperature and relative humidity monitors were available. Fire extinguishers were available. Computerized system (UPA) was Available and suitable for its intended use.
11. Qualification and validation	Procedure for data logger calibration was reviewed. There was procedure for deviations investigations These procedures were reviewed and found accepted. There were thermal mapping studies for cold room was executed. And The cold room thermal study report, The identified deficiency was addressed following the implementation of the submitted CAPA.
12. Personnel	Written procedures were in place for training SOP. There were adequate number of personnel to carry out all necessary activities. Training plan was provided, training Records for each employee were available. There was SOP for safety & hygiene, were reviewed and found accepted.
13. Documentation	In general, documents were regularly reviewed, procedure for good documentation practice. That ensure regular review of data for consistency with ALCOA+, it was reviewed and found accepted.
14. Activities and operation	**Receiving & Dispatch:** Written procedures were in place for receiving & Dispatch of products SOP. The SOP was reviewed and found accepted. Medical products were supplied from appropriately authorized suppliers, and deliveries were examined for damage, seal intactness, signs of tampering, labelling and completeness of the order at the time of receiving, also ensure that products were dispatched, in accordance with documented requirements and guidelines. **Storage** There was written procedures of storage management in cold room for storage of products & Storage in refrigerator &for storage in freezer Products were stored in accordance with their requirements. There were SOP for handling of spillage Also, written procedures

	were in place for cleaning SOP. Written procedures were in place for pest control SOP. There were written procedures for fire control. They were reviewed. **Distribution and transport** There were procedures for transportation of pharmaceutical products pharmaceutical products were transported and distributed in accordance with documented requirements. It was reviewed and found accepted. The identified deficiency was addressed following the implementation of the submitted CAPA.
15. Outsourced activities	Procedure for outsourcing activities and contracting with service provider was in place. It was reviewed and found accepted.
16. Substandard and falsified products	Written procedures were in place for substandard and falsified products SOP. These procedures outline steps for identifying and segregating such products to prevent them from being distributed. 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, (مخازن طعوم مديريات الشئون الصحية - القاهرة) Located at (مستشفى الحميات امتداد شارع رمسيس -القاهرة), 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