EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the site	مخزن طعوم مديريه الشئون الصحيه بالشرقيه
Inspected site	
Address of inspected site	ديوان المديريه – شارع مدير الامن –خلف مبني المحافظه –الزقازيق- محافظه الشرقيه
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 medical products, no raw material, hazardous or narcotic stored in the site.
Assessment of the Site Master File (SMF) if present	There was SMF 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	There was designed, documented and correctly implemented

(QMS)	quality management system to ensure that the quality of the products is maintained throughout supply chain, SOP of SOP. There was a written quality manual. The roles and responsibilities of personnel were clearly defined and understood by all individuals involved. These were documented through written job descriptions form and there was an authorized organizational chart in place to indicate the responsibilities and interrelationships of personnel within the organization form. SOPs were reviewed and found accepted.
2. Quality risk management (QRM)	There was a system to assess, control, communicate and review risks identified at all stages in the supply chain, the sop was reviewed .specified a risk team to manage risk process. The evaluation of risk based on scientific knowledge. Risk assessments coded were reviewed and found accepted.
3. Management Review	The management review process SOP indicates periodic management reviews, opportunities for continual improvement and follow-up on recommendations from previous meetings. Minute and related documentation were reviewed and found accepted.
4. Complaints	There was a written procedure for the handling of complaints. Complaints procedures differentiated between complaints about the product and those related to the service offered by the warehouse. It was reviewed and found accepted.
5. Returned goods.	Written SOP was in place for handling returned products. Returned goods were assessed for quality issues and stored in a secure location while decisions were made regarding their further use or destruction. Examination of the returned goods, with decisions taken by suitably qualified, experienced and authorized persons. Returned goods were controlled centrally via UPA. SOP for destruction of rejected and expired products was reviewed and found accepted.
6. Recalls	A comprehensive system for handling product recalls was in place. This system 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. SOP Mock There was mock recall was performed successfully and the results shows that the recall system was effective and capable of ensuring product traceability, were reviewed and found accepted.
7. Self-inspection	Internal audits, or self-inspections, were conducted according to the warehouse procedures to ensure compliance with quality

	standards as per SOP .Self-inspections were conducted periodically, according to an annual plan. The results of self-inspections were recorded. Reports contain all observations made during the inspection. Report of self-inspection was reviewed and found accepted, CAPAs was taken within a defined timeframe.
8. Premises	The premises in the warehouse were air conditioned. Sufficient space, lighting and ventilation to ensure required segregation and appropriate storage conditions. The storage area was secured with access controls to prevent unauthorized entry, There was a fire control system. Temperature were monitored at regular intervals and recorded.
9. Stock control and rotation	Written procedures for stock control and product rotation, were in place to ensure that products were stored properly and used before their expiration dates and first expired first out procedures was followed. Periodic monthly stock reconciliation was performed by comparing the actual and recorded stock. Documents were reviewed and found accepted.
10. Equipment	All equipment appropriately designed, located, installed, qualified and maintained. The computerized system was capable of achieving the desired access level. SOP for preventive maintenance was in place. The identified deficiency was addressed in the submitted CAPA.
11. Qualification and validation	SOP of qualification and validation was in place. Thermal mapping studies was conducted for cold room and found accepted The identified deficiency was addressed in the submitted CAPA.
12. Personnel	The warehouse had a sufficient number of personnel to carry out all necessary activities. There were Safety procedures in place written procedure for health, hygiene There were training programs in place according to SOP Training was provided to ensure that staff were equipped with the necessary knowledge and skills to perform their duties. Training plan was available. Training attendance were reviewed and found according to plan System was reviewed and found accepted.
13. Documentation	Documentation practices were well-structured; with document control SOP .The SOP was reviewed and found accepted. Written procedures for the preparation, review, approval, use of and control of all documents relating to the policies and activities were in place.
14. Activities and operation	**Receiving:** the procedure of receiving SOP was reviewed and

	found accepted **Storage:** the procedure of storage in cold room SOP, in refrigerators and in freezers and procedures of handling with spillage and breakage Pest control program was in place were reviewed and found accepted **Dispatch:** the procedure of dispatching SOP was reviewed and found accepted. **Distribution and Transport:** the procedure of distribution and transportation was reviewed and found accepted
15. Outsourced activities	There were no activities relating to the storage and distribution of medical product that was delegated to another person or entity. SOP was in place was reviewed and found accepted.
16. Substandard and falsified products	SOP for handing of falsified and substandard products 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 ديوان المديريه – شارع مدير الامن –خلف مبني المحافظه** (**طعوم مديريه الشئون الصحيه بالشرقيه الزقازيق- محافظه الشرقيه**), 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