EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the site	مخزن طعوم مديرية الصحة بمحافظة دمياط
Inspected site	
Address of inspected site	ديوان المديرية- ميدان باب الحرس – محافظة دمياط
Inspection details	
Dates of inspection	26/1/2026
Type of inspection	***local, planned, and announced***
Scope	
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 products
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 for the warehouse It was 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 roles and responsibilities of personnel were clearly defined and understood by all individuals involved. These were documented There was an organization chart. .through written job descriptions There was a quality policy, and all procedures were approved by the responsible manager, dated and signed. It was reviewed and found accepted.

2. Quality risk management (QRM)	SOP of quality risk management, code was reviewed. There was a system to assess, control, communicate and review risks identified at all stages in the supply chain to address all risks. The evaluation was based on scientific knowledge. Record of risk was reviewed and found accepted. There was Risk assessment for storing of products in the refrigerators and freezers was reviewed and found accepted.
3. Management Review	SOP of management review, was reviewed. the management review process involved senior management. Minute of meeting held on time was reviewed and found accepted**.**
4. Complaints	Handling of customer complaint SOP, was reviewed and found accepted. Regarding complaints related to quality of a medical product or its packaging, the original manufacturer and/or marketing authorization holder was informed as soon as possible.
5. Returned goods.	Written procedures were in place for handling returned products SOP. The SOP was reviewed and found accepted. These procedures ensured that returned goods were assessed for quality issues while decisions were made regarding their further use or destruction.
6. Recalls	SOP of recall was reviewed. These procedures ensured that products were recalled efficiently clear throughout the process. In SOP there were communication with manufacturer or the MAH, customers and EDA. There was mock recall was performed successfully and the results shows that the recall system was effective and capable of ensuring product traceability. Record of mock recall was reviewed and accepted.
7. Self-inspection	Self-inspection SOP was reviewed and found accepted as the team of self-inspection had appropriate knowledge, experience with quality standards. Record of final audit report and its CAPAs was reviewed and found accepted.
8. Premises	Premises had enough lighting. There were air conditioners. Temperature was recorded at regular interval. There was sufficient security, there were pest traps and insect killers.
9. Stock control and rotation	Written procedures were in place for stock reconciliation SOP was reviewed and found accepted. Stock control and product rotation were in place to ensure that products were stored properly and used before their expiration dates. This system maintaining product quality by ensuring that older stock is used before newer stock. There was daily stock reconciliation.
10. Equipment	The computerized systems (UPA) were capable of achieving the desired outputs and results. Firefighting equipment were available and serviced regularly. It was reviewed and found accepted.

	The identified deficiency was addressed by the warehouse in submitted CAPA.
11. Qualification and validation	There was a written procedure for qualification and validation .There were access levels for computer system and the traceability was done and the quantity was identical was reviewed and its data were found complete. Thermal validation study for the cold room was done. There were open door and power failure challenge tests. The identified deficiency was addressed by the warehouse in submitted CAPA.
12. Personnel	SOP of training was reviewed. The company employed enough qualified personnel to carry out all necessary activities. Record of training assessment was reviewed and found accepted. She was trained on GSDP.
13. Documentation	By reviewing documentation SOP was found accepted as documentation was handled according to established procedures with ALCOA+ principles and there were back-up and restoration of data regarding to documentation system in the warehouse.
14. Activities and operation	**Receiving and dispatch** Activities were carried out according to procedure to ensure that the correct product is delivered from the correct supplier. The receiving and dispatch processes were separated by time. It was reviewed and found accepted. **Storage** **S**torage SOP was reviewed and found accepted. Written procedures were in place for pests controlPremises were protected against entry of birds, insects and other animals. Written procedures were in place for cleaning SOP. Were reviewed and found accepted. **Distribution and transport** Procedures for vehicles transport was reviewed and found accepted. Vehicles were checked for cleaning and the medical products were transported in the conditions stated on the labels and described by the manufacturer.
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	Handling of counterfeit products 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 طعوم مديرية الصحة بمحافظة دمياط) Located at (ديوان المديرية- ميدان باب الحرس – محافظة دمياط), 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