EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the site	**مخزن الطعوم والامصال بمديرية الشؤن الصحية بالدقهلية**
Inspected site	
Address of inspected site	المنصورة – ديوان المديرية – خلف استاد المنصورة – مستشفى المنصورة الدولى – دقهلية
Inspection details	
Dates of inspection	26/1/2025
Type of inspection	**Local, planned, and announced** inspection.
Scope	
Scope	This is a routine inspection conducted over products distributors' warehouse within the execution of the EDA 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 products.
General information about the site	
General information about the site	**مخزن الطعوم والامصال بمديرية الشؤن الصحية بالدقهلية** is working in the distribution of medical products, no row 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 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 SOP for (QMS) and an appropriate organizational structure was established, and operations were clearly defined through written procedures. They were reviewed and found accepted.
2. Quality risk management (QRM)	QRM was conducted based on SOP it was reviewed. This procedure outlined the process for controlling, communicating, and reviewing risks at every stage of the supply chain. Risk assessment for storing of the products in the refrigerators and freezers was reviewed and found accepted.
3. Management Review	SOP for management review was reviewed and found accepted as management review process involved senior management and focused on reviewing the overall effectiveness of the quality system. Management review meeting was held on time and was reviewed and found accepted.
4. Complaints	SOP for handling customer complaints was reviewed and found accepted as complaints were handled according to established procedures that ensured proper investigation and corrective actions were taken if needed. Log book for complaints was reviewed and found accepted.
5. Returned goods.	SOP for handling returned goods was reviewed and found accepted. Returned goods were stored in a separated area. Destruction of products was done according to SOP, it was reviewed and found accepted.
6. Recalls	SOP for recalls was reviewed and found accepted. There were separated, secured area for Recalled products. Mock recall was performed successfully and the results shows that the recall system was effective and capable of ensuring product traceability. Was reviewed and found accepted.
7. Self-inspection	SOP for self-inspection was reviewed and found accepted. Self-inspection was done according to plan, its CAPA was done Records were reviewed and found accepted.

8. Premises	Premises had enough lighting. Receiving and dispatch bays were separated. There was an air conditioning system in the warehouse. Temperature were controlled, monitored at regular intervals in the warehouse and refrigerator, records sheets were available.
9. Stock control and rotation	SOP for stock control and rotation was reviewed and found accepted. Products are stored properly and used before their expiration dates. The inventory was performed successfully and the results shows that the recall system was effective and capable of ensuring product traceability
10. Equipment	Equipment used with appropriate design, and suitably located for its intended use and it was properly maintained. There was SOP was reviewed. Firefighting equipment were available and served regularly. Computerized system (UPA system). The identified deficiency was addressed by the warehouse in the submitted CAPA.
11. Qualification and validation	There was SOP for qualification and validation was reviewed. Thermal mapping study for two cold room was performed The identified deficiency was resolved following the implementation of the submitted CAPA.
12. Personnel	There was adequate number of personnel. SOP for training SOP for safety), SOP for health and hygiene, they were reviewed and found accepted. There was training performed on Quality management system on time.
13. Documentation	Documentation practices were well-structured. Records were maintained. Good documentation system SOP it was reviewed and found accepted as documentation system was well-structure and maintained.
14. Activities and operation	Activities and operations were specified in written procedures SOP. It was reviewed and found accepted **1.1. <u>Receipt</u>** Medical products were supplied from authorized suppliers according to SOP and delivers were examined before entered storage area on form. it was reviewed and found accepted **1.2. <u>Storage</u>** Medical products were stored in accordance with their storage requirements. SOP for Storing in refrigerators. SOP for Storing in freezers, SOP for Storing in cold room

	and SOP for handling of spillage and breakage they were reviewed and found accepted. SOP for temperatures monitoring and SOP for cleaning were reviewed and found accepted. . The warehouse was protected from the entry of insects, rodent and birds according to SOP.SOP for fire control were reviewed and found accepted. The warehouse was following FEFO arrangement. Documents were reviewed and found accepted. **1.3. Distribution and transport** Distribution processes were carried out according to SOP Vehicles loading were based on (LIFO) basis, it was examined on form for the available vehicles during the visit **14.4. Dispatch** Activities related to dispatch processes were carried out according to SOP it was reviewed and found accepted. Records of dispatch included full data, was reviewed and found accepted
15. Outsourced activities	There was 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.
16. Substandard and falsified products	There was SOP for handling substandard or falsified products 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, (**مخزن الطعوم والامصال بمديرية الشؤن الصحية بالدقهلية**) Located at (خلف استاد المنصورة – ديوان المديرية المنصورة – مستشفى المنصورة الدولى – دقهلية), 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