EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the site	مخزن طعوم مديرية الشئون الصحية بالإسماعلية
Inspected site	
Address of inspected site	ديوان المديرية خلف مجمع المحاكم - الإسماعلية
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 imported drugs distributors and importers' warehouse within the execution of 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	مخزن طعوم مديرية الشئون الصحية بالاسماعيلية is one of the warehouses in Egypt that located in ديوان المديرية خلف مجمع المحاكم - الاسماعيلية , specialized in storing vaccines.
Assessment of the Site Master File (SMF) if present	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	Egyptian Drug Authority Good Storage and Distribution Practice World Health Organization Biological Products Inspection Administration

CAPA SOPs QMS QRM	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)	Quality manual was available, and the roles and responsibilities were defined as written job description according to SOP. There was an authorized organizational chart. It was reviewed and found accepted.
2. Quality risk management (QRM)	The company conducts Quality Risk Management (QRM) based on an established risk management procedure SOP. This procedure outlined the process for assessing, controlling, communicating, and reviewing risks at every stage of the supply chain. Documents were reviewed and found accepted. - Risk study for storing of products in the refrigerators and freezers were reviewed and found accepted.
3. Management Review	Regarding management review, it was done according to SOP. Last management review was held on time. It was reviewed and found accepted.
4. Complaints	Regarding handling of complaints, the activity was done according to SOP of handling complain. Complaints were classified to (critical-major-minor). Complaints were identified, recorded, and appropriate CAPAs were taken according to SOP. They were reviewed and found accepted.
5. Returned goods.	Regarding handling of returned goods, these products would be assessed and stored in segregated location. Handling of returned products was done in accordance with SOP .The SOP was reviewed and found accepted.

6. Recalls	Regarding handling of recalled products, it was done according to SOP. Mock recall was done annually. There was mock recall was performed successfully and the results shows that the recall system was effective and capable of ensuring product traceability. The SOP was reviewed and found accepted.
7. Self-inspection	Regarding self-inspection, the activity was done according to SOP. Criteria for self-inspection team selection were clearly clarified. Last self-inspection was reviewed and all CAPAs were finished within the defined timeframe. They were reviewed and found accepted
8. Premises	Premises had enough lighting and ventilation. There was one cold room. Premises were suitably located, designed, constructed and maintained, to ensure appropriate operations such as storage, cleaning, and picking of medical products. There were pest traps and insect killers.
9. Stock control and rotation	Regarding stock control, it was found to be done annually according to SOP. Stock discrepancies were identified and appropriate CAPAs were taken. There was regular check for expired products. They were reviewed and found accepted.
10. Equipment	Equipment used were appropriately designed, and suitably located for its intended use and it was properly maintained. Data loggers were calibrated according to SOP. It was reviewed and found accepted. The identified deficiency was addressed in the submitted CAPA.
11. Qualification and validation	Regarding the scope of qualifications and validation, the computer system was capable of achieving the desired output. Deviation was handled according to SOP. It was reviewed and found accepted. -Thermal mapping study for the cold room protocol was reviewed and found accepted. Door opening and power failure challenge tests were executed. The identified deficiency was addressed in the submitted CAPA.

12. Personnel	Regarding personnel, sufficient number was available and they received initial and continued training according to written SOP. Training plan was reviewed and found accepted. SOP for personnel health, clothing and hygiene, was reviewed and found accepted.
13. Documentation	Documentation control was done in accordance with SOP. It was reviewed and found accepted
14. Activities and operation	- Activities and operations were performed in accordance with documented procedures SOP, was reviewed and found accepted. **Receiving** Receiving SOP were reviewed and found accepted. **Storage** There was SOP for handling of spillage SOP for pest control program, SOP for safety were reviewed and found accepted. SOP of security manual was reviewed and found accepted. Receiving and dispatching bays were separated by time. Cleaning was done according to SOP was reviewed and found accepted. **Transportation** Transportation was done according to SOP. It was reviewed and found accepted.
15. Outsourced activities	Regarding outsourced activities, there were no activities related to the storage and distribution of medical products that were delegated to third parties. was reviewed and found accepted.
16. Substandard and falsified products	Regarding handling substandard goods, it was done according to 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 ديوان المديرية خلف مجمع المحاكم - الإسماعلية) Located at (طعوم مديرية الشئون الصحية بالإسماعلية), 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