EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the site	مخزن طعوم مديرية الشئون الصحية
Inspected site	
Address of inspected site	ديوان المديرية – شارع النبوى المهندس - المسلة – بندر الفيوم
Inspection details	
Dates of inspection	26/1/2026
Type of inspection	***local, planned, and announced***
Scope	
Scope	This 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	this is one of warehouse in مخزن الطعوم بمديرية الشئون الصحية – الفيوم Egypt. The warehouse is working on the distribution of Vaccines, no raw material, hazardous or narcotic stored in the site.
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 roles and responsibilities of personnel were clearly defined and understood by all individuals involved, and recorded as written job descriptions, SOP. There was an authorized organizational chart, to

	indicate the responsibilities and interrelationships of personnel within the organization. There was a written quality manual, describing the overall intentions and requirements regarding quality. They were reviewed and found accepted.
2. Quality risk management (QRM)	SOP, there was a system to assess, control and review risks at all stages in the supply chain. The evaluation of risk was based on scientific knowledge and experience. The effectiveness of these controls was periodically evaluated. Risk of storage of medical products was reviewed and found accepted.
3. Management Review	SOP, the management review process involved senior management and focused on reviewing the overall effectiveness of the quality system. This was done by using quality metrics and key performance indicators (KPIs). The review process also identified areas for continual improvement and ensured that follow-up actions were taken based on recommendations from previous management reviews. The last minutes of the meeting was on time and the related documents and inputs were available. The SOP was reviewed and found accepted.
4. Complaints	SOP, differentiated between the complaints that may relate to the quality of the product, or the service offered by the warehouse to ensure appropriate action was promptly taken. Each complaint was evaluated to determine if it could indicate a wider issue affecting multiple batches of the product. No complaints were received in the warehouse. The SOP was reviewed and found accepted.
5. Returned goods.	SOP was in place. There was a separated place for returned goods while decision was made. The logbook of returned products which were kept for a defined period. The SOP was reviewed and found accepted.
6. Recalls	SOP the system included notifying regulatory authorities and all relevant stakeholders in the event of a recall. The traceability of product movement was checked manual and was found to be easily accessible. The process ensured that products were recalled efficiently, and that communication was clear throughout the process. Mock recall was considered manual. The SOP was reviewed and found accepted.
7. Self-inspection	SOP, there was a periodic self-inspection conducted for checking the compliance with quality standards. Last inspection done on time.

	Corrective actions are taken based on the results of these audits by form. The SOP was reviewed and found accepted.
8. Premises	Premises included separate areas for receiving and dispatching area by time. There were sufficient space, lighting and ventilation to ensure required segregation. There were pest traps and insect killers. There was fire extinguisher.
9. Stock control and rotation	There was SOP for periodic stock reconciliation, it was performed at defined intervals, by comparing the actual and recorded stock. The products were stored properly and used before their expiration dates the last stock control and rotation was conducted successfully and properly documented. The “first expired first out “rule was followed. The SOP was reviewed and found accepted.
10. Equipment	Equipment was appropriately designed, located, installed, qualified and maintained. The computerized system in the warehouse was (UPA). SOP of equipment maintaining. There was a list of equipment. The identified deficiency was addressed by the warehouse in the submitted CAPA.
11. Qualification and validation	SOP, Thermal mapping study for cold room was conducted, protocol and report. The identified deficiency was addressed by the warehouse in the submitted CAPA.
12. Personnel	The warehouse employed a sufficient number of personnel to carry out all necessary activities. Training was provided to ensure that staff are equipped with the necessary knowledge and skills to perform their duties according to the annual training plan. The records, attendance and evaluation sheets of training on SOP training, Training sheet was reviewed. Training of warehouse employees and personal hygiene and health SOP. Documents were reviewed and found accepted.
13. Documentation	Documentation practices were well-structured, with written procedures in place for all major activities. Most records, including temperature and humidity logs, were maintained to ensure compliance with storage requirements. Document control was handled according to established procedures, ensuring that documents were reviewed and updated regularly. Document control SOP was reviewed and found accepted.
14. Activities and operation	All key activities, including the receiving, storage, dispatch, and

	transportation of products, were carried out according to documented procedures. **Receiving**: Receiving drugs SOP was reviewed and found accepted. The code of receiving products inspection list was reviewed and found accepted. **Storage:** Storage of baits in refrigerators SOP Storage of baits in freezers SOP, Storage of baits in cold rooms SOP, Handling of spillage of products SOP were reviewed and found accepted. There was a sanitation program available according to SOP Storage area was secured with access control to prevent unauthorized entry. There was enough, working and maintained fire extinguishers that have been distributed all over the warehouse, SOP. The products were stored off the floor, away from walls and ceilings, protected from direct sunlight. There was a pest control program available according to SOP. The temperature and relative humidity were monitored at regular intervals, monitoring of temperature SOP. Cleaning equipment and cleaning agents were separated from areas where products were handled. The SOPs were reviewed and found accepted. **Distribution and transport:** Transportation of pharmaceuticals SOP was reviewed and found accepted. The code of truck inspection list was reviewed and found accepted
15. Outsourced activities	Regarding outsourced activities SOP was reviewed and found accepted. There were no activities related to the storage and distribution of medical products.
16. Substandard and falsified products	Handling of counterfeit products SOP was reviewed. The 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 الشئون الصحية) Located at (ديوان المديرية – شارع النبوى المهندس - المسلة – بندر الفيوم), 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