EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the site	مخزن الطعوم بمديرية الشئون الصحية بالقليوبية
Inspected site	
Address of inspected site	أمام كلية الهندسة مخازن مديرية الشئون الصحية بنها الجديدة القليوبية
Inspection details	
Dates of inspection	26/1/2026.
Type of inspection	Local, planned and announced GSDP 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 Vaccines, 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	Egyptian Drug Authority Good Storage and Distribution Practice World Health Organization Biological Products Inspection Administration Corrective and Preventive Action

SOPs QMS QRM	Standard Operating Procedures Quality Management System Quality Risk Management
Part 2	**Brief summary of the findings and comments**
1. Quality management system (QMS)	-There was a written quality policy SOP that describing the overall intentions and requirements regarding quality and there was data integrity policy for the warehouse. It was reviewed and found accepted. -There was organizational chart. SOP for the warehouse. -All procedures were approved by the responsible manager, dated and signed. It was reviewed and found accepted.
2. Quality risk management (QRM)	-SOP for QRM SOP was reviewed and there was a system to assess, control, communicate and review risks identified at all stages in the supply chain to address all risks using RPN, risk assessment for storing products in the refrigerators was reviewed and found accepted.
3. Management Review	There was a system for periodic management according to procedure for management review SOP, It was reviewed and found accepted. The record of the implemented management review minute was held on time. The record was reviewed and found accepted.
4. Complaints	Handling of customer complaint SOP was reviewed and found accepted. There was classification for the incoming complaints to (critical-major-minor) with defined time frame of response for each class. It was reviewed and found accepted.
5. Returned goods.	Handling of returned goods SOP code was reviewed and found accepted. Returned products separated and placed in quarantine upon receipt, were reviewed and found accepted.
6. Recalls	The company had in place a system for promptly managing recalls in accordance with procedure SOP code the implemented mock recall was performed successfully and the results shows that the recall system was effective and capable of ensuring product traceability, It was reviewed and found accepted.
7. Self-inspection	-Procedure for self-inspection SOP was reviewed and found accepted. The records of the self-inspection conducted and the implementation of SOPs of GSDP were reviewed and found

	accepted.
8. Premises	Premises were suitably located, designed, constructed and maintained, to ensure appropriate operations. There were pest traps and insect killers, Temperature were monitored and recorded. There was a sanitation program in place and there was efficient security.
9. Stock control and rotation	Procedure for stock control and rotation was reviewed and found accepted. There was a check for expired and near expired products and those products were segregated for disposal. The records were reviewed and found accepted.
10. Equipment	There were two walk-in cold rooms in the warehouse and eight fridge tags for routine monitoring of temperature in the cold rooms and in the site The identified deficiency was addressed by the warehouse in the submitted CAPA.
11. Qualification and validation	-Procedure for qualification of computer system There was a calibration program and the uniformity of the temperature across the storage facility according to validation SOP It was reviewed and found accepted. - The thermal study for the two cold room protocol was reviewed The identified deficiency was resolved following the implementation of the submitted CAPA.
12. Personnel	-Procedures for training SOP was reviewed and found accepted. Initial, continued and on job training were conducted. The training records in on the implementation of GSDP, were reviewed and found accepted.
13. Documentation	-In general, documents were regularly reviewed and procedure for document control SOP was reviewed and found accepted. The overwriting and correction fluid was not allowed.
14. Activities and operation	Activities and operations were performed in accordance with documented procedures according to Daily activities SOP was

	reviewed and found accepted. **-Receiving:** -Activities related to receiving process SOP was reviewed and found accepted. The incoming delivery checked against the relevant documentation to ensure that the correct product is delivered from the correct supplier and the receiving and dispatch processes were separated by time. All data related to the products and the suppliers were completely recorded. The records were reviewed and found accepted. **-Storage:** -There was a written procedure for handling spillage/breakage of materials SOP code was reviewed and found accepted. -Handling of rejected goods SOP was reviewed and found accepted. **-Dispatch:** -Activities related to dispatching process SOP,All data related to the products and the customers were recorded. The written related procedures were reviewed and found accepted. **- Distribution and Transport:** -Procedures for transportation SOP was reviewed and vehicles were checked for cleaning and the temperature before loading.
15. Outsourced activities	All activity relating to the storage and distribution of a medical product that is delegated to another person or entity performed by the appropriately authorized parties, in accordance with national legislation and the terms of a written contract, with SOP was reviewed and found accepted.
16. Substandard and falsified products	Handling the substandard, falsified and rejected products was according the SOP. 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 بمديرية الشئون الصحية بالقليوبية) Located at (أمام كلية الهندسة مخازن مديرية الشئون الصحية بنها الجديدة القليوبية), 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. short name: WHO TRS No. 1025, Annex 7 https://www.who.int/publications/m/item/trs-1025-annex-7