EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the site	**Menoufia Vaccine Warehouses**
Inspected site	
Address of inspected site	Shibin El Kom Teaching Hospital, Faculties Street, Shebeen El koom, El Minofia
Inspection details	
Dates of inspection	26/01/2026
Type of inspection	***Local, planned, and announced*** inspection.
Scope	
Scope	This is a routine inspection conducted over finished products distributors and importers' warehouses 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, 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 Vaccines; no raw materials, hazardous, or narcotics are stored on the site.
Assessment of the Site Master File (SMF) if present	There was an SMF for the warehouse was reviewed and maintained in accordance with the applicable requirements.
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)	A documented Quality manual were in place, clearly outlining the organization's overall commitment to quality. An appropriate organizational structure was established, and operations were clearly defined through written procedures. As clarified in the job description SOP the Quality management system was reviewed and found accepted.
2. Quality risk management (QRM)	A risk management system was established in compliance with GSDP guidelines to assess, control, communicate, and review risks. Risk evaluations were conducted based on scientific knowledge. The quality risk management was reviewed and found accepted. Risk assessment for the receiving and dispatching area was reviewed and found accepted.
3. Management Review	The management review process, led by senior management, was conducted to assess the overall effectiveness of the quality management system. The review focused on identifying opportunities for continual improvement and ensured that corrective actions were implemented based on the outcomes and recommendations from prior management reviews. Last management review was reviewed and found accepted.
4. Complaints	Complaints were managed by established procedures, ensuring appropriate classification into product-related complaints and those concerning services provided by the warehouse. The procedure is outlined in SOP. Complaint SOP and records were reviewed and found accepted.
5. Returned goods.	The returned products were managed by established procedures, ensuring that returned goods were assessed for quality issues and stored in a secure location while decisions were made regarding their further use or destruction. The procedure is outlined in SOP. The returned goods SOP and records were reviewed and found accepted.
6. Recalls	The recalled products were managed by established procedures, ensuring that the recalled products were recalled efficiently, including notifying regulatory authorities. There was mock recall

	was performed successfully and the results shows that the recall system was effective and capable of ensuring product traceability. It has been reviewed and found to follow the written procedure. The recalled products' SOP and records were reviewed and found accepted.
7. Self-inspection	Self-inspections were carried out by the company's procedures to verify compliance with established quality standards. The procedure is documented in the SOP .These audits serve to identify areas for improvement and ensure that all quality-related activities align with regulatory requirements. The internal audit report was reviewed and found to follow the written procedure. The self-inspection was reviewed and found accepted.
8. Premises	The company's premises included secured, segregated areas for recalled, returned products, and expired products. The receiving and dispatching operations were time-separated. The storage area was secured with access controls to prevent unauthorized entry; temperature was monitored and recorded within regular intervals.
9. Stock control and rotation	Written procedures for stock control and product rotation were established to ensure proper storage of products before their expiration dates. These procedures are outlined in the SOP. This system helps maintain product quality by prioritizing the use of older stock before newer stock. Stock control and rotation were reviewed and found accepted.
10. Equipment	All equipment is appropriately designed and located, and the computer system (UPA) is capable of achieving the desired output, where there were secured passwords for individuals, and an allocation system was in place, which was reviewed by challenging some products and computer system managed to produce reports about sales, returned products, products quantities and all required operations for managing products stock and storage. The identified deficiency has been adequately addressed within the warehouse CAPA.
11. Qualification and validation	There was a validation SOP for the computer system, and a thermal validation study for the two cold room was executed The identified deficiency was resolved following the implementation of the submitted CAPA
12. Personnel	The company maintained an adequate number of qualified personnel to perform all required activities. Training was provided to ensure that staff possessed the necessary knowledge and skills to effectively carry out their responsibilities. Structured

	training programs were in place, as outlined in SOP .Training records of GSDP principals for the store personnel were reviewed and found to follow written procedures, and there were written procedures covering the health and hygiene of personnel outlined in SOP. The training SOP and records were reviewed and found accepted
13. Documentation	Documentation practices were well-established and governed by written procedures, as detailed in SOP Procedures were in place to ensure that all major activities were appropriately documented. The Documentation was reviewed and found accepted.
14. Activities and operation	All critical activities, including vaccines transport into storehouse SOP vaccines storage in cold rooms SOP and in fridges were conducted in compliance with established company policies to ensure that product quality was consistently maintained throughout the supply chain. These SOPs were reviewed and found accepted. Cleaning SOP and pest control SOP and safety SOP were reviewed and found accepted.
15. Outsourced activities	There was SOP for outsourced activities. Although, no activity relating to the storage and distribution of a medical product that is delegated to another person or entity.
16. Substandard and falsified products	SOP for substandard and falsified product procedures were 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, (Menoufia Vaccine Warehouses) Located at (Shibin El Kom Teaching Hospital, Faculties Street, Shebeen El koom, El Minofia), 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**
	• 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 • 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