EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the site	**Vaccine warehouse Alexandria health Affairs Directorate**
Inspected site	
Address of inspected site	El Nabawy El Mohandes ST. beside Occupational Safety and Health Center- Alexandria
Inspection details	
Dates of inspection	26/1/2026
Type of inspection	**local, planned, and announced** 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	Vaccine warehouse Alexandria health Affairs Directorate 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 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	Egyptian Drug Authority Good Storage and Distribution Practice World Health Organization Biological Products Inspection Administration Corrective and Preventive Action Standard Operating Procedures

QMS QRM	Quality Management System Quality Risk Management
Part 2	**Brief summary of the findings and comments**
1. Quality management system (QMS)	Regarding to QMS, it was ensured through well-defined procedures, job descriptions, processes, clear organizational chart and responsibilities for the workers. There was quality manual it was reviewed and found accepted. All SOPs were reviewed and found signed and dated by the QA manager. All forms and records attached to the SOPs were reviewed and accepted.
2. Quality risk management (QRM)	Regarding to quality risk management, there was SOP, it was signed and dated by responsible persons, it was reviewed and found accepted. The QRM principles were found understood by the warehouse. Risks were identified at all stages in supply chain, There was risk about separation between the receiving and delivery areas. was reviewed and found accepted.
3. Management Review	Regarding to management review, SOP it was signed and dated by responsible persons, it was reviewed and found accepted. Management reviews were conducted regularly. Records of last meeting and related documents were reviewed and found accepted.
4. Complaints	Regarding to handling complaints, SOP was reviewed and found accepted as each complaint was categorized and investigated.
5. Returned goods.	Regarding returned goods system, SOP was reviewed and found accepted. Returned products had been inspected and evaluated by responsible persons and were stored in quarantine area according to storage conditions until their disposition. There were specific criteria for returning products with special storage conditions to stock. Returned goods logbook coded it was reviewed and found accepted. Last record was reviewed and found accepted. There was written procedure for handling rejected and expired products it was reviewed and found accepted, the destruction of rejected products was in accordance with international, national and local requirements with consideration to the protection of the environment.
6. Recalls	Regarding to recall system, SOP it was signed and dated by responsible persons, it was reviewed and found accepted. Recalled

	products were secured, segregated, transported and stored under appropriate conditions. Communication with the EDA was found in the recall SOP. Mock recall was done once /year and where necessary. Last 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 completed.
7. Self-inspection	Regarding to self-inspection, SOP it was dated and signed by responsible persons. Self-inspection team was found independent. There was annual self- inspection plan. Last record according to the plan it was reviewed and found accepted.
8. Premises	Premises were suitably designed to all operations with sufficient lightening. There was access control to avoid theft. Three air conditioning system covered the storage area. Air curtain was found in the entrance of the store. Allocation system was found in the store. Vaccines were stored in segregated areas that were clearly marked. Temperature was recorded regularly. There was sanitation program indicating the frequency of cleaning and methods to be used in cleaning it was signed and dated by responsible persons, it was reviewed and was found accepted. Product removed from saleable stock were segregated physically in specific area. Premises were protected from the entry of birds, pest and insects.
9. Stock control and rotation	Procedure for stock control and rotation, it was signed and dated by responsible persons, it was reviewed and was found accepted. Periodic stock reconciliation performed at defined intervals by comparing the actual and recorded stock. Stocks were checked regularly for expired goods. Last inventory was performed successfully and properly documented was reviewed and found accepted in form). Investigation for stock discrepancies was identified and CAPA taken. Records of stock for all products was kept and maintained in paper form
10. Equipment	There was a list of equipment designed and located Computer system (UPA) was designed to perform different tasks and each user had a specific username. Regular backup of computer system was performed. Traceability of products in supply chain was performed manually. Firefighting equipment were available and serviced regularly. There was one digital thermometer for the

	store. Calibration of data loggers and digital thermometers were performed according to SOP; the identified deficiency was addressed by the warehouse in the submitted CAPA.
11. Qualification and validation	Regarding to qualification and validation, there was written procedure for qualification and validation. Thermal validation study for the cold room was conducted it was reviewed and was found accepted. Risk reports for storage in the deep freezers were reviewed and were found accepted. There was written procedure for computer system validation it was reviewed and found accepted, The identified deficiency was addressed by the warehouse in the submitted CAPA.
12. Personnel	There were adequate numbers of educated persons, Procedure for training it was found signed, dated by the responsible persons, it was reviewed and was found accepted. There was a training plan. Last training was conducted for fire evacuation plan training and records of all training, evaluation and attendance were reviewed and found accepted. There were written procedures cover health, hygiene and clothing. There were written procedures cover personnel and environment safety. SOPs were reviewed and found accepted.
13. Documentation	Regarding to documentation system. There was written procedure for documentation system it was found signed, dated by the responsible persons All activities were performed according to written procedures. Documents were found completed, reviewed and kept as required. Records were maintained for the back-up and restoration of data, it was reviewed and found accepted.
14. Activities and operation	**-<u>Receiving</u>:** Regarding to receiving processes. They were carried out according to Procedure, it was found signed, dated by the responsible persons, and it was reviewed and was found accepted. Receiving done by responsible persons. Records for each consignment were reviewed and found completed. Last consignment was reviewed and found accepted. -**<u>Storage:</u>** Activities relating to storage processes were carried out according to Procedure in the cold room and storage in the deep freezer SOP they were found signed, dated by the responsible

	persons, they were reviewed and were found accepted. Medical products were stored in accordance with requirements. Records of temperature were done regularly. Storage area was fully separated from receiving and dispatching areas. Products were stored away from ceiling, walls and sunlight. There were written procedures to prevent and handle spillage and breakage), it was reviewed and was found accepted. -**Dispatch:** Regarding to dispatching was reviewed and was found accepted. Records of dispatch were containing sufficient information and product identity were maintained. **- Distribution and Transport:** Activities related to distribution were carried out according to Procedure it was reviewed and was found accepted. This activity is not performed by the store as each customer is responsible for the transportation of its products.
15. Outsourced activities	Regarding to outsourced activity. There was a written procedure for outsourced activities it was reviewed and was found accepted.
16. Substandard and falsified products	Regarding to handling the counterfeit product, SOP was reviewed and was 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, (**Vaccine warehouse Alexandria health Affairs Directorate**) Located at (El Nabawy El Mohandes ST. beside Occupational Safety and Health Center- Alexandria), 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