EDA Public Inspection Report (GSDP)

Part 1	General information
Inspected site details	
warehouse information	
Name of the site	MOH vaccine storage areas
Inspected site	
Address of inspected site	51 Wezaret Al Zeraa, Al Agouzah, Al Dokki- Giza
Inspection details	
Dates of inspection	01/01/2026
Type of inspection	**Local, announced, planned** inspection.
Scope	
Scope	This is a planned inspection conducted over imported products distributors and importers' warehouse within the execution of the 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 Storage and distribution of Vaccine and Located 51 Wezaret Al Zeraa, Al Agouzah, Al Dokki- Giza.
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 CAPA SOPs QMS QRM	Egyptian Drug Authority Good Storage and Distribution Practice World Health Organization 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 QMS was ensured through written quality manual .There was organizational chart in place to indicate the responsibilities and interrelationships of personnel within the organization. There was job Description SOP that helps ensure that each person's duties are clearly

	understood and aligns with the quality objectives of the warehouse. Job description for Warehouse pharmacist & warehouse mangers were reviewed and found that it clearly defines roles, responsibilities & qualifications needed. The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection.
2. Quality risk management (QRM)	QRM was conducted based on SOP, it was signed and dated by QA manager. It 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 failure mode and effect analysis (FMEA) tool. Risk assessment reports were reviewed and found satisfactory. The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection.
3. Management Review	There was written SOP. The management review process involves senior management and focused on reviewing the overall effectiveness of the quality system. Last meeting was held on time. Documents were reviewed and found accepted. The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection.
4. Complaints	Handling of customer complaint SOP was reviewed and there was classification for the incoming complaints to (critical-major-minor). Each complaint is evaluated to determine if it could indicate a wider issue affecting multiple batches of the product. The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection.
5. Returned goods.	Handling of returned goods SOP are in place. These procedures ensure that returned goods are assessed for quality issues and stored in a secure location while decisions are made regarding their further use or not. Also, SOP for rejected products was reviewed and found accepted. The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection.
6. Recalls	There was written procedure for recall .There was secured, segregated area for recalled products. Communication with the EDA was found in the recall SOP. There was mock recall was performed successfully and the results shows that the recall system was effective and capable of ensuring product traceability. The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection.
7. Self-inspection	Procedures for self -inspection. There was periodic self-inspection conducted according to annual plan. The team conducting the inspection was independent

	and competent. Records of self-inspection were reviewed. Last self-inspection report was reviewed and found accepted The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection.
8. Premises	Premises was consisted of 13 refrigerator and 1 freezer, air-conditioned receiving area and 5 refrigerators (one out of use) and 1 freezer (empty and out of use) in the dispatch area. There was sufficient security in the refrigerators. There was lab guard system for monitoring temperature 24 hrs. And it was having alarm system. There were steel racks and plastic pallets. Sufficient lighting and ventilation to ensure required appropriate storage conditions and cleanliness. Receiving and dispatch activities were separated. There was allocation system. Also, written procedures were in place for cleaning. Written procedures were in place for pest control. There were written procedures for fire control. The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection.
9. Stock control and rotation	Written procedures were in place for stock control and rotation, to ensure that products were stored properly and used before their expiration dates as (first expired first out) rule was followed. Periodic stock reconciliation performed at defined intervals by comparing the actual and recorded stock. The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection.
10. Equipment	Equipment used appropriately designed, and suitably located for its intended use and it was properly maintained. Temperature and relative humidity monitors were available as there were calibrated sensors (lab guard sys.). Fire extinguishers were available. Computerized system (UPA) was Available. The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection.
1. Qualification and validation	Procedure for data logger calibration, was reviewed. There was procedure for deviations investigations. These procedures were reviewed and found accepted. There were thermal mapping studies for 4 cold-rooms. The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection.
12. Personnel	Written procedures were in place for training. There were adequate number of personnel to carry out all necessary activities. Training plan was provided, training records for each employee were available. There was SOP for safety & hygiene were reviewed and found accepted. The identified deficiency was addressed by the warehouse in the submitted

	CAPA and were verified during the follow up inspection.
13. Documentation	In general, documents were regularly reviewed, procedure for good documentation practice cod. That ensure regular review of data for consistency with ALCOA+, was reviewed and found accepted. The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection.
14. Activities and operation	**Receiving & Dispatch:** Written procedures were in place for receiving & Dispatch of products. The SOP was reviewed and found accepted. Medical products were supplied from appropriately authorized suppliers, and deliveries were examined for damage, seal intactness, signs of tampering, labelling and completeness of the order at the time of receiving, also ensure that products were dispatched, in accordance with documented requirements and guidelines. **Storage** There was written procedures of storage management in cold room, for storage of products &for storage in freezer. Products were stored in accordance with their requirements. There were SOP for handling of spillage **Distribution and transport** There were procedures for transportation of pharmaceutical products. Pharmaceutical products were transported and distributed in accordance with documented requirements. It was reviewed and found accepted. The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection.
15. Outsourced activities	Procedure for outsourcing activities and contracting with service provider was in place It was reviewed and found accepted. Contract between Vacsera and MOH was reviewed and found accepted as it had the required quality agreements The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection.
6. Substandard and falsified products	Written procedures were in place for substandard and falsified products. These procedures outline steps for identifying and segregating such products to prevent them from being distributed. The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection.

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, (MOH vaccine storage areas) Located at (51 Wezaret Al Zeraa, Al Agouzah, Al Dokki- Giza), 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	**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