EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the site	مخزن الطعوم و الأمصال بمديرية الشئون الصحية بالغربية
Inspected site	
Address of inspected site	شارع سعيد بجوار مركز طبي سعيد – مدينة طنطا / محافظة الغربية
Inspection details	
Dates of inspection	26\1\2026
Type of inspection	***local, planned, and announced***
Scope	
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 products
General information about the site	
General information about the site	) is مخزن الطعوم و الأمصال بمديرية الشئون الصحية بالغربيةThe warehouse (dedicated to the storage and distribution of vaccines and sera only, no raw material, hazardous or narcotic stored in the site.
Assessment of the Site Master File (SMF) if present	The Site Master File) was reviewed and found to be in compliance with the guideline for drafting Site Master File, Annex 14 of the 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)	A quality management system was established to ensure compliance with standard procedures and to support continuous improvement. A written quality manual was available, describing the overall quality requirements.

	There was an authorized organizational chart. indicating the responsibilities, authorities, and interrelationships of personnel, and including all job titles. It was reviewed and accepted. The roles and responsibilities of personnel were clearly defined and understood by all involved individuals. These were documented through written job description procedures .The personnel file of the General Manager was reviewed, including the job description All SOPs had the approval of top management and were properly dated and signed.
2. Quality risk management (QRM)	The Quality Risk Management (QRM) system Procedure was conducted to identify potential risks, evaluate their impact, and ensure that appropriate control measures were implemented. There was Risk assessment for storing of products in the refrigerators and freezers was reviewed and found accepted.
3. Management Review	A system for periodic management review was in place, covering key discussion points, recommendations, and opportunities for continual improvement. The top management meeting included the introduction and implementation of quality policies. The management review report for the las meeting included a summary of recommendations, responsible management, implementation timelines, and follow-up actions. It was reviewed and found accepted.
4. Complaints	The system for managing and recording complaints was implemented to ensure proper investigation and implementation of corrective actions, as required. Complaints related to the quality of sera and vaccines or to the services provided by the warehouse were classified as critical, major, or minor. It was reviewed and found accepted.
5. Returned goods.	The procedure for handling returned goods was implemented to ensure that returned products are checked and assessed by a qualified and trained person for product condition and the attached documents, and that the reason for return was stated in the return records. The product return request form and the annual returns log It was reviewed and found accepted. The procedure for destructed and rejected products was in place It was reviewed and found accepted.
6. Recalls	The system for promptly managing recalls It was reviewed and found accepted as it was implemented to ensure compliance with

	defined requirements. The system is checked annually and includes a classification for recalls (critical, major, and minor) with a defined timeframe for each class. A mock recall was conducted using the distribution form . The recall process report was reviewed, and the effectiveness of the recall process was 100%. The mock recall log It was reviewed and found accepted.
7. Self-inspection	The self-inspection procedure was implemented to ensure that periodic self-inspections are conducted according to the approved annual self-inspection plan for. The internal inspection team was identified using form .Documents were reviewed and found accepted. An internal inspection was conducted in accordance with the review point's checklist. The final report and the corrective actions report for non-conformities, were reviewed and found accepted.
8. Premises	The premises were designed and equipped to facilitate appropriate operations, with access restricted to authorized personnel only. Receiving and dispatch operations are performed in accordance with clearly defined and posted instructions. The warehouse consists of two cold rooms where vaccines are stored using an allocation system**.** One of the cold rooms is equipped with an air-conditioning system. The warehouse contains four deep freezers: two horizontal and two verticals. Two of these freezers are designated for emergency use. Additionally, there are two emergency refrigerators available for use. Temperature monitoring was implemented, recommending continuous temperature monitoring and comply with storage requirements for each vaccine. Digital temperature recording devices (Fridge Tag) were used. The temperature and daily vaccine movement recording form, as well as the maximum and minimum temperature recording form, were reviewed and found accepted.
9. Stock control and rotation	Stock control and rotation were performed in accordance with the documented procedure.The monthly inventory report was reviewed and found accepted, and no discrepancies were observed between the actual stock and the recorded stock level.
10. Equipment	The equipment was appropriately designed, located, installed, qualified, and maintained. The procedure for equipment maintenance was implemented. The periodic equipment maintenance monitoring form was reviewed. The warehouse uses a

	unified electronic system. The procedure for equipment coding was implemented. The equipment coding form was reviewed and approved. The identified deficiency was addressed by the warehouse in the submitted CAPA.
11. Qualification and validation	The Qualification and Validation procedure was reviewed and found implemented to ensure that all equipment, systems, and processes are suitable for their intended purpose. Thermal mapping studies were conducted two for cold rooms. The identified deficiency was addressed by the warehouse in the submitted CAPA.
12. Personnel	Procedures for training warehouse personnel were established to ensure staff competence and qualification, as well as training on Good Storage and Distribution Practices (GSDP). The training annual plan was prepared in accordance with form). The training needs form was reviewed. An external training program on Good Storage and Distribution Practices (GSDP) was conducted. The attendance sheet was reviewed. In addition, the training record of the trainee. The trainer evaluation form was reviewed and accepted. Occupational Health and Safety procedures were implemented to ensure a safe working environment and compliance with warehouse quality requirements.
13. Documentation	Documentation procedures was reviewed and found accepted as it was implemented to ensure the accuracy, authorization, and proper control of records, including their review and approval. The ALCOA+ principles for record review were applied, and a change control request was submitted. Records were maintained in a timely manner, ensuring that all entries are attributable, legible, and accurate. Periodic audits of the documentation system were performed to verify compliance with established procedures.
14. Activities and operation	**Receiving and dispatch:** The standard operating procedure for operational activities which defines the handling and distribution of vaccines and sera from the Ministry of Health central warehouses to health directorates, and from directorates to health administrations, was implemented. The receiving and dispatch forms were reviewed and accepted. **Storage:** The procedures for storing vaccines in refrigerators were

	implemented. These procedures recommend storing vaccines at a temperature range of 2–8 °C and using digital temperature monitoring devices (Digital Fridge Tag). The temperature recording and daily vaccine movement form, the maximum and minimum temperature recording form, and the vaccine identification card form were reviewed and approved. The procedure for storing vaccines in freezers and the procedure for storing vaccines in cold rooms were implemented. The cold room emergency plan was available and reviewed and found accepted. Cleaning procedures were implemented in accordance with the procedure and the daily cleaning form was reviewed and found accepted. The warehouse security procedure was also established. The pest control procedures were implemented. The periodic trap monitoring form and the monthly trap inspection form were reviewed. Occupational health and safety procedures were in place. A fire-fighting system is available on-site, including a fire extinguisher maintenance card and a fire alarm monitoring card. Spillage and breakage handling procedure for vaccines and sera. They were reviewed and found accepted. **Distribution and transport:** The standard operating procedure for the transportation of vaccines and sera was implemented to ensure that vaccines are transported within the required temperature conditions and protected from damage or theft. Transportation is carried out using refrigerated vehicles or insulated cold boxes in accordance with the approved transportation instructions. The refrigerated vehicle inspection and monitoring form was reviewed and found accepted.
15. Outsourced activities	The procedure for contracting with outsourced activities was reviewed and accepted. The list of approved service providers were reviewed and accepted.
16. Substandard and falsified products	The procedure for handling counterfeit products was reviewed and 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 شارع سعيد بجوار مركز طبي سعيد – مدينة طنطا Located at)الطعوم و الأمصال بمديرية الشئون الصحية بالغربية محافظة الغربية /), 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