EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the site	مخازن مديريات الشئون الصحية بسوهاج
Inspected site	
Address of inspected site	مدينة ناصر – ديوان مديرية الصحة – بجوار مديرية الشباب والرياضة – محافظة سوهاج
Inspection details	
Dates of inspection	22/1/2026
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	The warehouse is working in the storage and 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.
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)	There was a written quality policy that describing the overall intentions and requirements regarding quality and there was data integrity policy for the company. There was organizational chart for the warehouse. There was written job description. 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 was reviewed and there was a system to assess, control, communicate, review risks identified at all stages in the supply chain to address all risks using failure mode and effect analysis (FMEA) tool. There was Risk assessment for storing of products in the refrigerators and freezers was reviewed and found accepted.
3. Management Review	There was a system for periodic management according to procedure for management review for the quality system and its effectiveness with client satisfaction and identification of opportunities for continual improvement. The last meetings about requirement for GSDP. Action assessment taken. It was reviewed and found accepted
4. Complaints	By reviewing SOP of Complaints were handled according to established procedures that ensure proper investigation and corrective actions were taken if needed. It was reviewed and found accepted.
5. Returned goods.	Returned goods SOP was reviewed and found accepted as it outlined the handling of the returned products from receiving until the final disposition.
6. Recalls	The company had in place a system for promptly managing recalls in accordance with procedure was reviewed. The progress of a recall process checked, which includes reconciliation between delivered and recovered quantities of medical products. Mock recall was performed and it was reviewed and found accepted.
7. Self-inspection	Procedure for self -inspection, was reviewed and there was periodic self-inspection conducted and the last audit performance, the self-inspection team should be trained and

	certified. The last self-inspection was performed and its report and CAPA taken after internal audit was reviewed and found accepted.
8. Premises	There was air condition system. The shelves were made of metal. The pallets were made of plastic. -There were separated secured areas for recalled, falsified, expired and rejected products into cold room. -There was separated secured area for returned products. There were separate receiving and dispatch bays by time. -Premises had enough lighting and there was sanitation program. -The products were stored off the floor, away from walls and ceilings, protected from direct sunlight and suitably spaced, to permit ventilation, cleaning and inspection. -The Temperature were monitored at regular intervals and recorded.
9. Stock control and rotation	Procedure for Stock control and rotation was reviewed and there was a check for expired and near expired products and those products were segregated for disposal. The last one was performed successfully. It was reviewed and found accepted.
10. Equipment	Procedure for Equipment was reviewed. The computer system used for controlling and monitoring storage and distribution of goods was UPA The identified deficiency was addressed by the warehouse in the submitted CAPA.
11. Qualification and validation	Procedure for Qualification and validation was reviewed. There was thermal mapping study for cold room The identified deficiency was addressed by the warehouse in the submitted CAPA.
12. Personnel	Procedures for training was reviewed and initial, continued and on job training was conducted. It was training about the chain of command and the emergency plan and GSDP, the assessment for trainees was reviewed for the attendee. There was training plan and implemented according to the plan. It was reviewed and found accepted.
13. Documentation	Documentation practices were well-established and governed by written procedures. It was reviewed and found accepted

14. Activities and operation	**-Receiving:** SOP Was reviewed. Received products were examined for damage. The incoming delivery was checked against to relevant documentation, to ensure that the correct product was delivered. It was reviewed and found accepted. **-Storage:** SOP for storage, was reviewed. Products stored off the floor and away from walls into cold room and deepfreezes also kept clean. It was reviewed and found accepted. -There was a written procedure for handling spillage/breakage of materials and It was reviewed and found accepted - Handling of expired goods SOP was reviewed and found accepted **-Dispatch:** Activities relating to dispatch processes were carried out according to Procedure. Batch no and expired date was written as in permission. It was reviewed and found accepted. **- Distribution and Transport:** Procedure for transportation control was reviewed and found accepted.
15. Outsourced activities	Procedure for Outsourced activities was reviewed. There was no activity relating to the storage or distribution of a medical product that is delegated to another person or entity.
16. Substandard and falsified products	Handling the substandard and falsified products was according the SOP 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, (مخازن مديريات الشئون الصحية بسوهاج) Located at (مدينة ناصر – ديوان مديرية الصحة – بجوار مديرية الشباب والرياضة – محافظة سوهاج), 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