EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the site	مخازن مديريات الشئون الصحية بالوادى الجديد
Inspected site	
Address of inspected site	الخارجة – امام مخازن ادارة الصيدلة – الوادى الجديد
Inspection details	
Dates of inspection	27/1/2026
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 distribution of medical products, no raw material, hazardous or narcotic stored in the site. The warehouse is licensed affiliated with the New Valley Health Affairs Diretorate..
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)	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 about separation between the receiving and delivery areas. It was reviewed and found accepted.
3. Management Review	There was a system for periodic management according to procedure for management review, effective date: 10/1/2026 for the quality system and its effectiveness with client satisfaction and identification of opportunities for continual improvement. The last one about requirement for reporting temperature deviations. Action assessment taken. It was reviewed and found accepted.
4. Complaints	By reviewing S0P of Complaints were handled according to established procedures that ensure proper investigation and corrective actions were taken if needed that done in central. It was reviewed and found accepted.
5. Returned goods.	Handling of returned goods SOP was reviewed. It was reviewed and found accepted.
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 manually, which includes reconciliation between delivered and recovered quantities of medical products. There was 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 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 on time. its report and CAPA taken after internal audit was reviewed and found accepted.
8. Premises	There is air condition system. The shelves in cold room are made of metal. The pallets are made of plastic. -There are separated secured areas for recalled, falsified, expired and rejected products into cold room. -There is separated secured area for returned products. There are 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.
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 stock control and rotation was conducted successfully and properly documented. It was reviewed and found accepted.
10. Equipment	The computer system used for controlling and monitoring storage and distribution of goods was UPA. The identified deficiency was addressed following the submitted CAPA.
11. Qualification and validation	Procedure for Qualification and validation was reviewed and accepted. There was thermal mapping study for cold room. The identified deficiency was addressed following the submitted CAPA.
12. Personnel	Procedures for training was reviewed and initial, continued and on job training was conducted. It was training about tanning on how to preserve vaccines and serums, There was assessment for trainees There was training plan It was reviewed and found accepted.
13. Documentation	Procedure for document control was reviewed and found accepted as it included procedure for controlling of all documents.
14. Activities and operation	**Receiving:** SOP was reviewed. Received products were examined for damage. The incoming delivery was checked by inspection report

	against to relevant documentation, to ensure that the correct product was delivered from the Serum and Vaccine. 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 rejected goods SOP was reviewed and found acceptable. - Handling of expired goods SOP was reviewed and found acceptable. -There was pest control program in place according to SOP for control of the rodents and for operation and maintenance of insect killers. -Procedure for fire control .The last services date was 1/2026. -The Temperature and relative humidity were monitored at regular intervals and recorded according SOP for deepfreezes and cold room. SOPs were 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 for El Kharga Administration. It was reviewed and found acceptable **Distribution and Transport:** Procedure for transportation control was reviewed and found accepted. There was list of authorized drivers.
15. Outsourced activities	Procedure for Outsourced activities was reviewed. There was list of service providers relating to the storage of a medical product
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 بالوادى الجديد) Located at (الوادى الجديد – امام مخازن ادارة الصيدلة (الخارجة, 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