EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the inspected site	EPX LOGISTICS
Inspected site	
Address of inspected site	Plot 2L01, Area No. 2 - Zizinia Communities - 10th of Ramadan - Sharkia
Inspection details	
Dates of inspection	27 /2 /2025
Type of inspection	***local, planned, and announced***
Scope	
Scope	Inspection 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	The warehouse is working in the distribution of medical products, no raw material, hazardous or narcotic stored in the site. The warehouse is licensed by EDA for this task license No 37 and date of issue of first license date of the site was 2019.
Assessment of the Site Master File (SMF) if present	It was found that complying with the guideline for drafting site master file (code NO 0005/02); 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 roles and responsibilities of personnel were clearly defined and understood by all individuals involved. These were documented through written job descriptions, and there was an authorized organizational chart in place to indicate the responsibilities and

	interrelationships of personnel within the organization. This chart helped ensure that each person's duties were clearly understood and aligned with the quality objectives of the warehouse.
2. Quality risk management (QRM)	The warehouse conducts Quality Risk Management (QRM) based on an established risk management procedure SOP. This procedure outlines the process for assessing, controlling, communicating, and reviewing risks at every stage of the supply chain. The system allows for the identification of potential risks that may impact the quality of products.
3. Management Review	The management review process involved senior management and focuses on reviewing the overall effectiveness of the quality system. The review process also identified areas for continual improvement. Last minutes was reviewed and found accepted.
4. Complaints	Complaints were handled according to established procedures that ensured proper investigation and classified to complaint handling product and that related to the service offered by the warehouse SOP was reviewed and found accepted.
5. Returned goods.	Written SOP were in place for handling returned products. These procedures ensured that returned goods assessed for quality issues and stored in a secure location while decisions were made regarding their further use or destruction.
6. Recalls	A comprehensive system for handling product recalls was in place. This system includes notifying regulatory authorities and all relevant stakeholders in the event of a recall. The process ensured that products were recalled efficiently and that communication was clear throughout the process. SOP was reviewed and found accepted.
7. Self-inspection	Internal audits, or self-inspections, were conducted according to the company's procedures to ensure compliance with quality standards. These audits help identify areas for improvement and ensure that all quality-related activities are in line with regulatory requirements. The self-inspection process was reviewed and found acceptable.
8. Premises	The premises in the warehouse include separated areas for receiving and dispatching goods. The storage area was secured with access controls to prevent unauthorized entry. The facility was equipped with fire control systems, including fire detection and firefighting equipment. In addition, a rodent and pest control program was in place to ensure cleanliness and product safety. 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 for stock control and product rotation were in place to ensure that products were stored properly and used before their expiration dates. This system helps maintain product quality by ensuring that older stock is used before newer stock.
10. Equipment	All the equipment appropriately designed, located and the computer capable of achieving the desired output. The identified deficiency was addressed by the warehouse in the submitted CAPA.
11. Qualification and validation	The site had in place procedures for performing qualification/validation facilities, equipment, and processes, the uniformity of the temperature across the storage facility was assured SOP for thermal mapping as there were Thermal validation study for the warehouse ambient (summer) and (winter), the warehouse mezzanine (summer) and (winter), and cold room 1) & cold room 2, and performance qualification protocol for inkjet. The identified deficiency was addressed by the warehouse in the submitted CAPA.
12. Personnel	The company had a sufficient number of qualified personnel to carry out all necessary activities. Training was provided to ensure that staff were equipped with the necessary knowledge and skills to perform their duties. There were training programs in place SOP was reviewed and found accepted.
13. Documentation	Documentation practices were well-structured, with written procedures SOP in place for all major activities. Records, including temperature and humidity logs were maintained to ensure compliance with storage requirements. Document control was handled according to established procedures SOP The identified deficiency was addressed by the warehouse in the submitted CAPA.
14. Activities and operation	All key activities, including the receiving and storage SOP, dispatch SOP, and transportation SOP were carried out according to documented procedures. These processes were managed in compliance with company policies to ensure product quality was maintained throughout the supply chain. The review of these activities showed compliance.
15. Outsourced activities	There was a written contract for pest control and fire system. Was reviewed and found accepted.
16. Substandard and falsified products	The company had procedures in place for handling substandard or falsified products. These procedures outline steps for identifying and segregating such products to prevent them from being

	distributed 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, (EPX LOGISTICS) Located at (Plot 2L01, Area No. 2 - Zizinia Communities - 10th of Ramadan - Sharkia), 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 manufacturer, 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