EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the site	Pharma overseas company trading and distribution of medicines
Inspected site	
Address of inspected site	Plot no,35- North expansions -polaris section-6 october -Giza.
Inspection details	
Dates of inspection	03/06/2025
Type of inspection	***local, planned, and announced***
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, self-inspection, Stock control and rotation, qualification and validation, activities and operations and 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 with licenses no.15 and date of issuing 2014.
Assessment of the Site Master File (SMF) if present	There was SMF for the warehouse, it was reviewed and found comply.
Abbreviations	
EDA	Egyptian Drug Authority
GSDP	Good Storage and Distribution Practice
WHO	World Health Organization
BPI	Biological Products Inspection Administration
CAPA	Corrective and Preventive Action
SOPs	Standard Operating Procedures
QMS	Quality Management System
QRM	Quality Risk Management

Part 2	Brief summary of the findings and comments
1. Quality management system (QMS)	The QMS was ensured through written quality policy quality manual, an authorized organizational chart in place to indicate the responsibilities and interrelationships of personnel within the organization, and documented written job descriptions that clearly defined roles and responsibilities, and written SOPs for all activities carried out. Documents were reviewed and found to be accepted.
2. Quality risk management (QRM)	The company conducted (QRM) based on an established risk management procedure SOP. This procedure outlined the process for controlling, communicating, and reviewing risks at every stage of the supply chain. The system allowed for the identification of potential risks that may impact the quality of products and appropriate control measures were developed and implemented to address these risks. Documents were reviewed and found to be accepted The identified deficiency was addressed by the warehouse in the submitted CAPA.
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. The review process also identified areas for continual improvement and ensured that follow-up actions were taken based on recommendations from previous management reviews. Documents were reviewed and found to be accepted.
4. Complaints	There was written SOP. to ensure appropriate recording, investigation and distinction between complaints. Documents were reviewed and found to be accepted. The identified deficiency was addressed by the warehouse in the submitted CAPA .
5. Returned goods.	Written procedures were in place for handling returned products SOP.These procedures ensured that returned goods were assessed for quality issues and stored in a secured location while decisions were made regarding their further use or destruction. There was SOP for receiving damaged and expired products. There was SOP for destruction of pharmaceutical waste.Destruction of rejected and expired products was done from the main expire warehouse of the company. Records of returned products were kept. Documents were reviewed and found to be accepted.
6. Recalls	Written procedures were in place for handling recalled products SOP. The procedure ensured that products were recalled efficiently

	clear and appropriate storage conditions and communication with EDA were considered. There were secured and segregated area for recalled products Documents were reviewed and found to be accepted. The identified deficiency was addressed by the warehouse in the submitted CAPA.
7. Self-inspection	Written procedures were in place for self-inspection SOP. The team of self-inspection was competent, independent and had appropriate knowledge and experience. Records of self-inspection were available. Documents were reviewed and found to be accepted.
8. Premises	Premises were suitably located, designed, constructed and maintained to ensure appropriate operations. Sufficient lighting and ventilation to ensure required appropriate storage conditions and cleanliness. There was air conditioning system. There was Sufficient security and receiving and dispatch bays were separated. Food, eating, drinking and smoking were prohibited. products were stored off the floor. Temperature and relative humidity were controlled, monitored at regular intervals by using calibrated instruments and kept for a suitable period. Written procedures were in place for cleaning SOP. Written procedures were in place for pests control SOP. Premises were protected against entry of birds and other animals. There were written procedures for fire control. Documents were reviewed and found to be accepted. The identified deficiency was addressed by the warehouse in the submitted CAPA.
9. Stock control and rotation	Written procedures were in place for stock control and rotation, SOP.to ensure that products were stored properly and used before their expiration dates as (first expired first out) rule was followed. Stock levels for products in the warehouse were maintained in electronic format and updated after each operation. Documents were reviewed and found to be accepted.
10. Equipment	Equipment used appropriately designed, and suitably located for its intended use and it was properly maintained in accordance to SOP for maintenance. Electric hoist and fork lift were present for transporting pallets between warehouse areas and for lifting pallets onto high storage racks. Cold rooms and temperature and relative humidity monitors were available. Firefighting system including fire alarms, extinguishers, boxes and hoses were available. Computerized system (SAP) was capable of achieving the desired outputs and results. Documents were reviewed and found to be accepted.
11. Qualification and validation	There was written SOP for validation and qualification. The site had in place procedures for performing qualification/validation to facilities, equipment, and processes. There were thermal mapping

	studies for the trucks and for warehouse and cold room. The warehouse winter study was conducted over a period of 7days). The cold room (R5) thermal study was conducted. Documents were reviewed and found to be accepted. The identified deficiency was addressed by the warehouse in the submitted CAPA.
12. Personnel	There were adequate numbers of qualified and experienced personnel to carry out all necessary activities Written procedures were in place for training SOP. Training was provided to ensure that staff were equipped with the necessary knowledge and skills to perform their duties. Records of training attendance and assessments were available. There was SOP covering safety. There was SOP covering hygiene. Documents were reviewed and found to be accepted.
13. Documentation	There was written SOP for control of documents. There was SOP for management of quality documents. There was SOP for archiving and filling. Documentation practices were well-structured, with written procedures in place for all major activities. Records, including temperature and humidity logs, were maintained to ensure compliance with storage requirements. Documents were reviewed and found to be accepted.
14. Activities and operation	Receiving and storage; Written procedures were in place for receiving and storage SOP. 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. The warehouse was equipped with overprinting machines through which the overprinting process was carried out in accordance with SOP for overprinting, The warehouse was following FEFO arrangement and products were stored in accordance with their requirements. There were written procedures for handling of spillage,it was reviewed and found accepted. Dispatch, Distribution and transport Written procedures were in place for distribution, and There were written procedures for product dispatching (picking and loading SOP),to ensure that products were dispatched, transported and distributed in accordance with documented requirements and guidelines. Vehicles used were adequately equipped and designed. There was global positioning system electronic tracking device to enhance the security and traceability. Distribution records were sufficient detailed and the name of drivers were included.

	Documents were reviewed and found accepted.
15. Outsourced activities	There was SOP for management of third party. There were written contracts and quality agreement that defined responsibilities. Documents were reviewed and found to be accepted.
16. Substandard and falsified products	Written procedures were in place for Substandard and Falsified products SOP. These procedures outline steps for identifying and segregating such products to prevent them from being distributed. There were secured and segregated area for such products. Documents were reviewed and found to be 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, (Pharma overseas company trading and distribution of medicines) Located at (Plot no,35-North expansions -polaris section-6 october -Giza.), was considered to be operating at an **acceptable** level in compliance with WHO GMP 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