EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the site	Pharma overseas trading and distribution of medicines
Inspected site	
Address of inspected site	Plot no,16- North expansions -polaris section-6 october -Giza.
Inspection details	
Dates of inspection	04/06/2025
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 a 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)	There was a written quality policy that describing the overall intentions and requirements regarding quality and there was data integrity policy for the warehouse. There was organizational chart for the warehouse. It was reviewed and found 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 duly executed, accepted and implemented. The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection
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 and implemented.
4. Complaints	There was written SOP to ensure appropriate recording and investigation of complaints. Documents were reviewed and found to be accepted.
5. Returned goods.	Handling of returned goods SOP was reviewed and found to be accepted and returned products separated and placed in quarantine upon receipt, Records of returned products were kept.
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.
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 executed,

	accepted and implemented.
8. Premises	There was sufficient space, lighting and ventilation that ensure required segregation appropriate storage condition and cleanliness. There was sanitation program available according to SOP indicating frequency of cleaning and methods to be used to clean the storage areas. 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. There was pest control program in place according to SOP for operation and maintenance of insect killers and pest. There was a written procedure for fire control and firefighting equipment available
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 executed, accepted and implemented.
10. Equipment	Equipment used appropriately designed, and suitably located for its intended use and it was properly maintained in accordance to SOP for Preventive 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 (PICK PACK) was capable of achieving the desired outputs and results. Documents were reviewed and found to be executed, accepted and implemented.
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 was SOP for deviation. There were thermal mapping studies for the trucks that were executed by the Egyptian engineering systems and for warehouse and cold room. The warehouse winter study was conducted over a period of 7 days. The cold room(R1) thermal study was conducted over a period of 3 days. 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 executed, accepted and implemented.
13. Documentation	There was written SOP for control of documents .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 executed, accepted and implemented.
14. Activities and operation	Receiving, Dispatch and storage; Activities relating to receiving and dispatch processes were carried out according to Procedure. The SOP was reviewed and the incoming delivery checked against the relevant documentation, to ensure that the correct product is delivered from the correct supplier and the receiving and dispatch processes were separated area , The warehouse was following FEFO arrangement and products were stored in accordance with their requirements. There were written procedures for handling of spillage. The product were stored according to the required specific storage condition according to the sop were reviewed and found implemented Distribution and transport Written procedures were in place for distribution. 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 to be executed, accepted and implemented.
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 executed and 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 executed 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,	

(Pharma overseas trading and distribution of medicines) Located at (Plot no,16- North expansions -polaris section-6 october -Giza.), 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