EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of site	مخزن شركة رامكو للأستيراد والتصدير والتوكيلات التجارية
Inspected site	
Address of inspected site	بجوار مصنع جلوبال للصناعات الدوائية – Aقطعة 2 المنطقة الصناعية الخامسة - مدينة 6 اكتوبر - محافظه الجيزة
Inspection details	
Dates of inspection	22/09/2026
Type of inspection	***local, planned, and announced*** inspection.
Scope	
Scope	This is a routine inspection conducted over imported products distributors and importers' warehouse within the execution of the annual inspection plan. The scope covers 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 located in 6 October city, Giza governorate and had licensed by EDA for this task with licenses no. (57/2018) And the date of first issuing was 20/12/2018.
Assessment of the Site Master File (SMF) if present	There was SMF was reviewed and found comply with the guideline for drafting site master file; Annex 14, WHO Technical Report Series, No.961, 2011.
Abbreviations	
EDA GSDP WHO BPI CAPA	Egyptian Drug Authority Good Storage and Distribution Practice World Health Organization Biological Products Inspection Administration Corrective and Preventive Action

SOPs QMS QRM	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 the quality manual. 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 helps ensure that each person's duties are clearly understood and align with the quality objectives of the company. - Quality Management system (QMS) reviewed and found accepted.
2. Quality risk management (QRM)	The company conducts Quality Risk Management (QRM) based on an established risk management procedure. 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, and appropriate control measures are developed and implemented to address these risks. The effectiveness of these controls is periodically evaluated to ensure they continue to mitigate risks effectively. - Quality Risk Management (QRM) system reviewed and found accepted.
3. Management Review	The management review SOP Involved senior management and focused on reviewing the overall effectiveness of the quality system, the last minutes were reviewed and found accepted.
4. Complaints	Complaints were handled according to SOP. That ensured proper investigation and corrective actions are taken if needed. Each complaint is evaluated to determine if it could indicate a wider issue affecting multiple batches of the product. -Complain system reviewed and found accepted.
5. Returned goods.	SOP were in place for handling returned products. These procedures ensure that returned goods are assessed for quality issues and stored in a secure location while decisions are made regarding their further use or destruction, All procedures reviewed and accepted.
6. Recalls	SOP Included notifying regulatory authorities and all relevant stakeholders in the event of a recall. The process ensured that products are recalled efficiently and that communication is clear

	throughout the process. -Log book for recalled product, report and mock recall were reviewed. -System was reviewed and found accepted.
7. Self-inspection	SOP was reviewed. Internal audits were conducted according to the company's procedures to ensure compliance with quality standards. -Self-inspections plan, report and Internal audit checklist. Self-inspections, reviewed and found accepted.
8. Premises	-Premises were suitably located, designed, constructed and maintained, to ensure appropriate operations such as storage, cleaning, and picking of medical products. - There was a sufficient security provided, and access controlled with SOP -There was a suitable air conditioning system to ensure proper storage conditions in the warehouse. -There were suitable temperature and relative humidity, controlled and monitored at regular intervals and recorded. -There was Appropriate controls and segregation for products requiring specific conditions such as hazardous substances. - Toilets, washing & rest facilities were separated from storage areas.
9. Stock control and rotation	Written procedures for stock control and product rotation are in place to ensure that products are stored properly and used before their expiration dates according to FEFO rules. -This system helps maintain product quality by ensuring that older stock is used before newer stock. -Stock Control report and Deviation report were reviewed. -Stock Control reviewed and found accepted.
10. Equipment	- Equipment used was with appropriate design and suitable for its intended use. It was properly maintained. List of equipment reviewed and found accepted.
11. Qualification and validation	-Qualification and Validation has SOP, SOP for calibration and SOP for computer system validation were reviewed. <u>- Thermal mapping exercise executed for summer and winter seasons, as follows:</u> - There were summer study and winter study for the warehouse store. - The cold room warehouse store unit 1 and The cold room

	warehouse store unit 2 -The study of the warehouse was conducted to ensure uniform temperature control throughout the facility. The data loggers used to monitor temperature were calibrated to ensure accuracy. The identified deficiency was addressed in the submitted CAPA.
12. Personnel	-The company employs enough qualified personnel to carry out all necessary activities. Training SOP Is provided to ensure that staff are equipped with the necessary knowledge and skills to perform their duties. -Safety procedures for personnel & appropriate procedures for environmental protection and product integrity. and the clothing of personnel and cover health hygiene SOP were reviewed and accepted. - Training about Printing operation procedure with attendance sheet and evaluation form, were reviewed and found accepted.
13. Documentation	- Documentation SOP were well-structured, with written procedures in place for all major activities. Records, including temperature and humidity logs, are maintained to ensure compliance with storage requirements. Document control is handled according to established procedures, ensuring that documents are reviewed and updated regularly. -Documentation procedures were reviewed and found accepted.
14. Activities and operation	Receiving SOP with investigation checklist recorded sheet, Storage of product SOP and Dispatching the product SOP were reviewed and found accepted. There was appropriate control to prevent and handle spillage and breakage. There was a written procedure for fire control including prevention of fire. -There was a pest control program in place with SOP. -Procedures for cleaning SOP was reviewed and found accepted. -Distribution of products related to third party. - These processes were managed in compliance with company policies to ensure product quality is maintained throughout the supply chain. The review of these activities showed compliance action. -All key activities were reviewed and found accepted.
15. Outsourced activities	-All key activities, related to outsourced activities and the entire process of the third party is subjected to the required quality agreements.

16. Substandard and falsified products	The company has SOP in place for handling counterfeit product. These procedures outline steps for identifying and segregating such products to prevent them from being distributed. It 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, مخزن شركة رامكو للأستيراد والتصدير والتوكيلات التجارية) Located at (بجوار مصنع جلوبال A قطعة 2 للصناعات الدوائية – المنطقة الصناعية الخامسة - مدينة 6 اكتوبر- محافظه الجيزة), was considered to be operating at an **acceptable** level of 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