EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouseinformation	
Name of site	شركة المكتب التجارى الدولى
Inspected site	
Addressofinspected site	الدور الالارضى – 7شارع الشهيد يسرى حلمى على – الساحل – القاهره
Inspection details	
Dates of inspection	15/6/2026
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 androtation, Qualification and validation, Activities and operations,Substandard and falsified product.
General information about the site	
General information about the site	International Trade Office is one of the warehouses in Egypt that located in 7 Shahid Yussri Helmy Ali street/ Sahal /Cairo with licenses no 33/ 2006 date of license of the site was 31/5/2006.
Assessmentofthe Site Master File (SMF)ifpresent	There was no SMF for the company.
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)	Regarding quality management system in the warehouse, job descriptions and organograms were reviewed. There were SOPs for activities carried out through the warehouse. The identified deficiency was addressed in the submitted CAPA.
2. Quality risk management (QRM)	Regarding quality risk management, The identified deficiency was addressed in the submitted CAPA.
3. Management Review	SOP of management review was reviewed. System was in place but regarding its implementation, the identified deficiency was addressed in the submitted CAPA.
4. Complaints	SOP of handling complaints was reviewed; there were different categorize for complaints. The identified deficiency was addressed in the submitted CAPA.
5. Returned goods.	SOP for handling of returned goods included checking for the data and quality of the received returned products, The identified deficiency was addressed in the submitted CAPA.
6. Recalls	System was established for handling of recalls and it was reviewed but regarding its implementation the identified deficiency was addressed in the submitted CAPA.
7. Self-inspection	SOP of self-inspection was reviewed and it included assigned team and checklist for quality aspects reviewed. The identified deficiency was addressed in the submitted CAPA.
8. Premises	Premises had enough lighting and space. There were fire extinguishers. The identified deficiency was addressed in the submitted CAPA.
9. Stock control and rotation	Regarding SOP for stock control and rotation, The identified deficiency was addressed in the submitted CAPA.
10. Equipment	There was one cold room in the warehouse and two data loggers for routine monitoring of temperature and relative humidity. The identified deficiency was addressed in the submitted CAPA.
11. Qualification and validation	Regarding the scope and extent of qualification and validation, The identified deficiency was addressed in the submitted CAPA.

12. Personnel	Regarding the personnel, there were enough number of personnel. The identified deficiency was addressed in the submitted CAPA.
13. Documentation	Regarding the documentation system in the warehouse, The identified deficiency was addressed in the submitted CAPA.
14. Activities and operation	Regarding receiving processes, activities relating to storage processes, activities relating to dispatch and transport process the identified deficiency was addressed following the implementation of the submitted CAPA.
15. Outsourced activities	Regarding the outsourced activities. The identified deficiency was addressed in the submitted CAPA.
16. Substandard and falsified products	Regarding substandard and falsified products. The identified deficiency was addressed in the submitted CAPA.
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, (شركة المكتب التجارى الدولى) Located at (الدور الالارضى – 7شارع الشهيد يسرى حلمى على – الساحل القاهره), 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