EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the site	SOFICO PHARMACEUTICALS S.A.E
Inspected site	
Address of inspected site	1 medan elsawah-general company for silos and storage-elzeitoun-Cairo
Inspection details	
Dates of inspection	**23/10/2023**
Type of inspection	***local, planned, and announced***
Scope	
Scope	This is a routine inspection conducted over warehouse within the execution of the 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, 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	Sofico pharmaceuticals S.A.E company was one of the warehouses in Egypt that located in 1 medan elsawah-general company for silos and storage-elzeitoun-Cairo with licenses no. 74 and date of issue of first license of the site was 2016.
Assessment of the Site Master File (SMF) if present	It was found that complying with the guideline for drafting site master file; Annex 14, WHO Technical Report Series, No.961, 2011.
EDA GSDP WHO BPI CAPA SOPs QMS QRM	Egyptian Drug Authority Good Storage and Distribution Practice World Health Organization Biological Products Inspection Administration Corrective and Preventive Action Standard Operating Procedures Quality Management System Quality Risk Management

Part 2	
1. Quality management system (QMS)	There was a written quality policy for the company, the roles and responsibilities were clearly defined and understood by the individuals concerned, and recorded as written job descriptions and there was an authorized organizational chart.
2. Quality risk management (QRM)	QRM was conducted based on SOP of enterprise risk management was reviewed, there was a system to assess, control, communicate and review risks identified at all stages in the supply chain and there were appropriate controls developed and implemented to address all risks and the effectiveness of the controls implemented were evaluated at periodic intervals.
3. Management Review	Procedure for management review was reviewed and found acceptable.
4. Complaints	Handling of customer complaint SOP was reviewed and all complaints recorded and appropriately investigated, The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection
5. Returned goods.	Handling of returned goods SOP was reviewed and found acceptable
6. Recalls	The company had in place a system for promptly managing recalls in accordance with procedure was reviewed and the progress of a recall process was recorded, all recalled products stored in secured and segregated area, The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection
7. Self-inspection	Procedures for self –inspection was reviewed and there was periodic self-inspection conducted, The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection
8. Premises	Premises were suitably located and constructed, to ensure appropriate operations and it had sufficient lighting and ventilation.
9. Stock control and rotation	Procedure for inventory control and rotation was reviewed and accepted.
10. Equipment	Equipment used with appropriate design, and suitably located for its intended use and it was properly maintained. The data loggers used for monitoring of temperature and humidity were calibrated, the

	operation qualification protocol for the computer system used for controlling and monitoring storage and distribution of goods was reviewed and accepted.
11. Qualification and validation	The uniformity of the temperature across the storage facility was assured as there were thermal validation study for the store, the refrigerators & vehicles, The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection
12. Personnel	There were adequate number of personnel , Personnel received initial and continued training ,Procedures for training was reviewed. The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection
13. Documentation	In general, documents were regularly reviewed. There was a sanitation program indicating the method and frequency of cleaning and it was accepted, almost all activities were performed according to written procedures, The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection
14. Activities and operation	Activities and operations were performed in accordance with documented procedures. **Receipt and Storage:** - Activities relating to Receiving 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. **Distribution and transport:** - Medical products were transported in accordance with the conditions stated on the labels and described by the manufacturer, Vehicles used for transportation of medical products were qualified to demonstrate their capability to maintain the required transport conditions and instruments used for monitoring conditions for example temperature and humidity within vehicles and containers were calibrated at regular intervals. **Dispatch:** - Activities relating to dispatch and delivery processes were carried out according to Procedure. The identified deficiency

	was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection
15. Outsourced activities	There wasn't any activity relating to the storage and distribution of a medical product that is delegated to another person or entity.
16. Substandard and falsified products	Handling the counterfeit drugs was according the SOP was reviewed and there was secure and segregated area for these products.
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, (SOFICO PHARMACEUTICALS S.A.E) Located at (1 medan elsawah-general company for silos and storage-elzeitoun-Cairo–), 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