EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the site	مستودع شركة سوفيكو فارما للادوية
Inspected site	
Address of inspected site	١٢١ ش اسماعيل القبانى مدينة نصر محافظة القاهرة
Inspection details	
Dates of inspection	23/6/2026.
Type of inspection	***local, planned and announced*** inspection.
Scope	
Scope	This is GSDP inspection conducted over the warehouse within the execution of 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 on 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
Assessment of the Site Master File (SMF) if present	There was SMF it was reviewed and found complying with the guideline for drafting site master file; Annex 14, WHO Technical Report Series, No.961, 2011.
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 SOP that describing the overall intentions and requirements regarding quality and there was data integrity policy for the warehouse. It was reviewed and found accepted. -There was organizational chart. SOP for the warehouse. -All procedures were approved by the manager responsible, dated and signed. It was reviewed and found accepted.
2. Quality risk management (QRM)	SOP for QRM SOP was reviewed and there was a system to assess, control, communicate and review risks identified at all stages in the supply chain to address all risks using RPN. It was reviewed and found accepted. The identified deficiency was in the submitted CAPA
3. Management Review	There was a system for periodic management according to procedure for management review SOP. It was reviewed and found accepted. The record of the last management review minute was on time. It was reviewed and found accepted.
4. Complaints	Handling of customer complaint SOP was reviewed and found accepted. There was classification for the incoming complaints to (critical-major-minor) with defined time frame of response for each classification. The last recorded complaint, Investigation record was reviewed and found accepted.
5. Returned goods.	Handling of returned goods SOP was reviewed and found accepted. Returned products separated and placed in quarantine upon receipt. The records were reviewed and found accepted.
6. Recalls	The company had in place a system for promptly managing recalls in accordance with procedure SOP. The record of recall. was reviewed and found accepted.
7. Self-inspection	Procedure for self-inspection SOP was reviewed and found accepted. The records of the self-inspection conducted on GSDP requirements, were reviewed and found accepted.
8. Premises	Premises had enough lighting, and products were stored off the floor, away from walls and ceilings, protected from direct sunlight and suitably spaced, to permit ventilation, cleaning and inspection. The identified deficiency was addressed by the warehouse in the submitted CAPA.
9. Stock control and rotation	-Procedure for stock control and rotation, was reviewed and

	found accepted. There was a check for expired and near expired products, and those products were segregated for disposal. The last stock control and rotation was conducted successfully and properly documented.
10. Equipment	There were three cold rooms in the warehouse and seven calibrated data loggers for routine monitoring of temperature and relative humidity that located in the worst locations according to the results of thermal mapping studies. The computer system used was SAP software. Regarding the access level, the function was achieved. It was reviewed and found accepted.
11. Qualification and validation	Procedure for qualification of computer system was reviewed. There was a calibration program. The uniformity of the temperature across the storage facility according to validation SOP was reviewed and found accepted. Summer thermal mapping study for the warehouse report protocol, winter thermal mapping study for the warehouse protocol , thermal mapping study for the first cold room protocol, thermal mapping study for the second cold room report protocol, thermal mapping study for the third cold room report protocol, and thermal mapping study for the vehicle protocol were all reviewed and found accepted.
12. Personnel	Procedures for training SOP code, were reviewed. Training records of the implementation of GSDP requirements were reviewed and found accepted.
13. Documentation	In general, documents were regularly reviewed and procedure for document control SOP was reviewed and found accepted. The overwriting and correction fluid was not allowed. -Procedure for good document practice SOP was reviewed and found accepted.
14. Activities and operation	-Activities and operations were performed in accordance with SOP. It was reviewed and found accepted. **-<u>Receiving</u>:** - Activities related to receiving process SOP, was reviewed and found accepted. 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. All data related to the products and the suppliers were completely recorded. The records were reviewed and found accepted. **-<u>Storage:</u>** -There was a written procedure for handling spillage/breakage of

	materials SOP. It was reviewed and found accepted. -Handling of rejected goods SOP was reviewed and found accepted. - There was sanitation program available according to SOP, indicating frequency of cleaning and methods to be used to clean the storage areas. -There were pest and the rodent control program in place according for control of the pest and rodent. -There was a written procedure for fire control, The firefighting equipment was available, reviewed and found accepted. -The Temperature and relative humidity were monitored at regular intervals and recorded according to SOP that was reviewed and found accepted. -**Dispatch:** -Activities related to dispatching process SOP, All data related to the products and the customers were recorded, the written related procedures were reviewed and found accepted. **- Distribution and Transport:** -Procedures for transportation SOP was reviewed and found accepted.
15. Outsourced activities	There was no activity relating to the storage or distribution of a medical product that is delegated to another person or entity.
16. Substandard and falsified products	Handling the substandard and falsified and rejected products was according to the SOP. It was reviewed and found accepted. The regulatory authority was informed of the results of investigations. - Regarding substandard and falsified products, storage and handling 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,(مستودع شركة سوفيكو فارما للادوية) Located at(١٢١ ش اسماعيل القبانى مدينة نصر محافظة القاهرة), 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