EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the site	مخزن طعوم مديرية الشئون الصحية بالسويس
Inspected site	
Address of inspected site	ديوان المديرية شارع البلدية بجوار مستشفي الحميات - السويس
Inspection details	
Dates of inspection	26/1/2026
Type of inspection	This is a **local, planned, and announced** inspection.
Scope	
Scope	This is a routine inspection conducted over imported drugs distributors and importers' warehouse within the execution of 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.
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Assessment of the Site Master File (SMF) if present	SMF 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)	Quality manual was available, and the roles and responsibilities were defined as written job description according to SOP. There was an authorized organizational chart. It was reviewed and found accepted.
2. Quality risk management (QRM)	SOP for QRM was reviewed and there was a system to assess, control, communicate, review risks identified at all stages in the supply chain to address all risks using failure mode and effect analysis (FMEA) tool. There was risk about separation between the receiving and delivery areas. It was reviewed and found accepted.
3. Management Review	Regarding management review, it was done according to SOP, last management meetings were available, and They were reviewed and found accepted.
4. Complaints	Regarding handling of complaints, the activity was done according to SOP of handling complain .It was reviewed and found accepted. Complaints were classified to (critical-major-minor). Complaints were identified, recorded, and appropriate CAPAs were taken according to SOP. It was reviewed and found accepted.
5. Returned goods.	Regarding handling of returned goods, these products would be assessed and stored in segregated location. Handling of returned products was done in accordance with SOP. It was reviewed and found accepted
6. Recalls	Regarding handling of recalled products, it was done according to

	SOP. Mock recall was done annually. The SOP was reviewed and found accepted.
7. Self-inspection	Regarding self-inspection, the activity was done according to SOP. Criteria for self-inspection team selection were clearly clarified. Plan was reviewed and report for the last internal audit was reviewed and found accepted.
8. Premises	There is air condition system. The shelves in cold room are made of metal. The pallets are made of plastic. -There are separated secured areas for recalled, falsified, expired and rejected products into cold room. -There is separated secured area for returned products. There are separate receiving and dispatch bays by time. -Premises had enough lighting and there was sanitation program. -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.
9. Stock control and rotation	Regarding stock control, it was found to be done annually according to SOP was reviewed and found accepted. Stock discrepancies were identified and appropriate CAPAs were taken. There was regular check for expired products.
10. Equipment	Equipment used were appropriately designed, and suitably located for its intended use and it was properly maintained. Data loggers were calibrated according to SOP was reviewed and found accepted. The identified deficiency was addressed following the submitted CAPA.
11. Qualification and validation	Regarding the scope of qualifications and validation, the computer system was capable of achieving the desired output. Deviation was handled according to SOP. It was reviewed and found accepted. -Thermal mapping study for the cold room protocol, report was reviewed and found accepted. Door opening and power failure challenge tests were executed. The identified deficiency was addressed following the submitted CAPA.

12. Personnel	Regarding personnel, sufficient number was available and they received initial and continued training according to written SOP. Training plan was reviewed and found accepted. SOP for personnel health, clothing and hygiene, was reviewed and found accepted.
13. Documentation	Documentation control was done in accordance with SOP. It was reviewed and found accepted as it included measures to apply ALCOA+ system.
14. Activities and operation	Activities and operations were performed in accordance with documented procedures SOP was reviewed and found accepted. **Receiving** Medical products were supplied from appropriately authorized supplier and deliveries were examined for damage, seal intactness, signs of tampering, labelling and completeness of the order at the time of receiving. **Storage** There was SOP for handling of spillage. SOP for pest control program, SOP for safety, were reviewed. SOP of security manual, was reviewed and found accepted. Receiving and dispatching bays were separated by time. Cleaning was done according to SOP. It was reviewed and found accepted. **Transportation** Transportation was done according to SOP. It was reviewed and found accepted.
15. Outsourced activities	Procedure for Outsourced activities was reviewed and found accepted. There was list of service providers relating to the storage of a medical product was reviewed and found accepted.
16. Substandard and falsified products	Regarding handling substandard goods it was done according to the approved SOP, 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	

	ديوان المديرية شارع البلدية بجوار مستشفي الحميات - السويس) Located at (طعوم مديرية الشئون الصحية بالسويس), 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