



Arab Republic of Egypt
Egyptian Drug Authority
Central Administration of Inspection
on Pharmaceutical Institutions
G.A. of factories inspection

جمهورية مصر العربية
هيئة الدواء المصرية
الإدارة المركزية للتفتيش
على المؤسسات الصيدلانية
إ.ع. التفتيش على المصانع

EDA Public Inspection Report (GSDP)

Part 1	General information
Inspected site details	
<i>warehouse information</i>	
Name of the site	مخازن طعوم مديريات الشئون الصحية باسيوط
<i>Inspected site</i>	
Address of inspected site	داخل مستشفى صدر اسيوط
Inspection details	
Dates of inspection	26/1/2026
Type of inspection	Local, planned, and announced inspection.
Scope	
Scope	This is a routine inspection conducted over the warehouse within the execution of 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	The warehouse is working in the distribution of vaccine, no raw material, hazardous or narcotic stored in the site.
Assessment of the Site Master File (SMF) if present	There was SMF was maintained and regularly updated It was reviewed and found comply.
Abbreviations	
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	Brief summary of the findings and comments



1. Quality management system (QMS)	There was a written quality policy that describing the overall intentions and requirements regarding quality and there was data integrity policy for the company. There was organizational chart for the warehouse. There was written job description. All procedures were approved by the responsible manager. Dated and signed. 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 assessment for storing of products in the refrigerators and freezers was reviewed and found accepted.
3. Management Review	There was a system for periodic management according to procedure for management review for the quality system and its effectiveness with client satisfaction and identification of opportunities for continual improvement.
4. Complaints	By reviewing SOP of complaints were handled according to established procedures that ensure proper investigation and corrective actions were taken when needed. It was reviewed and found accepted.
5. Returned goods.	Handling of returned goods was reviewed. The procedure covered the receipt, segregation, evaluation, investigation, documentation, and final disposition of returned products. It was reviewed and found accepted.
6. Recalls	The company had in place a system for promptly managing recalls in accordance with procedure was reviewed. The progress of a recall process checked manually, which includes reconciliation between delivered and recovered quantities of medical products. There was mock recall was performed successfully and the results shows that the recall system was effective and capable of ensuring product traceability. It was reviewed and found accepted.
7. Self-inspection	Procedure for self –inspection was reviewed and there was



	periodic self-inspection conducted and the last audit performance, the self-inspection team should be trained and certified. The last self-inspection was performed and its report and CAPA taken after internal audit was reviewed and found accepted.
8. Premises	There was air condition system. The shelves in cold room were made of metal. The pallets were made of plastic. -There were separated secured were as for recalled, falsified, expired and rejected products into cold room. -There was separated secured were a for returned products. -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	Procedure for Stock control and rotation was reviewed and 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 .It was reviewed and found accepted.
10. Equipment	Procedure for Equipment was reviewed, the computer system used for controlling and monitoring storage and distribution of goods was in place. The identified minor deficiency has been adequately addressed by the CAPA sent from the warehouse.
11. Qualification and validation	Procedure for Qualification and validation was reviewed and accepted. -There was thermal mapping study for cold room, it was completed The identified deficiency was resolved following the submitted CAPA.
12. Personnel	Procedures for training was reviewed and initial, continued and on job training was conducted. It was training about cold chain and bait movement and GSDP. The easement for trainees There was training plane. It was reviewed and found accepted.
13. Documentation	Procedure for document control. It was reviewed and found accepted as there was control of all documents within the SOP.



14. Activities and operation	-Receiving: SOP of receiving was reviewed. Received products were examined for damage. The incoming delivery was checked by inspection report against to relevant documentation. It was reviewed and found accepted. -Storage: SOP for storage was reviewed. Products stored off the floor and away from walls into cold room also kept clean. It was reviewed and found accepted. -There was a written procedure for handling spillage/breakage of materials and It was reviewed and found accepted - Handling of rejected goods SOP was reviewed and found acceptable. - Handling of expired goods SOP was reviewed and found acceptable. -There was pest control program in place according to SOP for control of the rodents and for operation and maintenance of insect killers. - Procedure for fire control was reviewed and found acceptable. And the fire extinguisher were serviced regularly. -The Temperature and relative humidity were monitored at regular intervals and recorded according SOP for deepfreezes and cold room. All SOPs was reviewed and found accepted. -Dispatch: Activities relating to dispatch processes were carried out according to Procedure .Batch no and expired date was written as in permission for East administration food warehouse. It was reviewed and found accepted. - Distribution and Transport: Procedure for transportation control was reviewed and there was list of authorized drivers.
15. Outsourced activities	Procedure for Outsourced activities including quality agreement, was reviewed and found accepted
16. Substandard and falsified products	Handling the substandard and falsified products was according the SOP 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, (مخازن طعام) (مدبرات الشؤون الصحية باسبوط) Located at (داخل مستشفى صدر اسبوط), was considered to be operating at an acceptable level in compliance with WHO GSDP standards as adopted by EDA.	



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- 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. short name: WHO TRS No. 1025, Annex 7 https://www.who.int/publications/m/item/trs-1025-annex-7