



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 بسيوط
<i>Inspected site</i>	
Address of inspected site	شارع الملك فيصل بجوار 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 Vaccines, no raw material, hazardous or narcotic stored in the site. The warehouse is licensed affiliated with the New Valley Health Affairs Directorate.
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 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 about freezing grafts and lack of a separate area for pick-up and delivery. It 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. The last one about training employees on quality standards. Action assessment taken. It was reviewed and found accepted.
4. Complaints	By reviewing SOP of Complaints were handled according to established procedures that ensure proper investigation and corrective actions were taken if needed that done in central. It was reviewed and found accepted.
5. Returned goods.	Handling of returned goods SOP 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 on time. About the SOPs of GSDP. CAPA was taken after internal audit, it 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, expired and



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	rejected products into cold room, There was separated secured area for returned products.
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 equipment in warehouse (Fridge tag) has valid according to its expiry date. The computer system used for controlling and monitoring storage and distribution of goods was UPA. It was reviewed and found accepted The identified deficiency was addressed in the submitted CAPA.
11. Qualification and validation	Procedure for Qualification and validation was reviewed and accepted. -There was thermal mapping study for cold room The identified deficiency was addressed in 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, The easement for trainees. There was training plane. It was reviewed and found accepted.
13. Documentation	Procedure for document control was reviewed and found accepted. As it included procedures to apply ALCOA+.
14. Activities and operation	-Receiving: SOP was reviewed. Received products were examined for damage. The incoming delivery was checked by inspection report against to relevant documentation. The product was delivered from the Serum and Vaccine. 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. -Premises had enough lighting and there was sanitation program



	available according to SOP indicating frequency of cleaning and methods to be used to clean the storage areas. -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. -There was pest control program in place according to SOP for control of the rodents and for operation and maintenance of insect killers. Was reviewed and found accepted -Procedure for fire control was reviewed and found accepted. They were serviced regularly. -The Temperature and relative humidity were monitored at regular intervals and recorded according to 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. It was reviewed and found acceptable. - Distribution and Transport: Procedure for transportation control was reviewed and found accepted, There was list of authorized drivers.
15. Outsourced activities	Procedure for Outsourced activities 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, (شارع الملك فيصل بجوار مستشفى صدر اسيوط) (مخازن طعوم مديريات الشؤون الصحية باسيوط), 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



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	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
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