



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	مخزن الطعوم بمديرية الشؤون الصحية بشمال سيناء
<i>Inspected site</i>	
Address of inspected site	ديوان المديرية-ح الريسة
Inspection details	
Dates of inspection	27/1/2026.
Type of inspection	Local, planned and announced GSDP 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 storage and distribution of Vaccines, no raw material, hazardous or narcotic stored in the site.
Assessment of the Site Master File (SMF) if present	There was 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 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	-There was a written quality policy SOP that describing the overall



(QMS)	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. 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, risk assessment for receiving and dispatching was reviewed and found accepted, they were reviewed and found accepted.
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 implemented management review minute was held on time The record 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 class. It 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, were reviewed and found accepted.
6. Recalls	The company had in place a system for promptly managing recalls in accordance with procedure SOP, The implemented 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 SOP was reviewed and found accepted. The records of the self-inspection conducted according to plan was for implementation of SOPs of GSDP, the records were reviewed and found accepted.



8. Premises	Premises were suitably located, designed, constructed and maintained, to ensure appropriate operations. There were pest traps and insect killers, Temperature were monitored and recorded. There was a sanitation program in place and there was efficient security.
9. Stock control and rotation	-Procedure for stock control and rotation was reviewed and found accepted as the procedure covered inventory control, stock rotation (FEFO/FIFO), stock reconciliation and periodic stock verification.
10. Equipment	There were two walk-in cold rooms in the warehouse and eight fridge tags for routine monitoring of temperature in the cold rooms and in the site The identified deficiency was addressed by the warehouse in the submitted CAPA.
11. Qualification and validation	Procedure for qualification of computer system was a calibration program and the uniformity of the temperature across the storage facility according to validation SOP. It was reviewed and found accepted. The thermal study for the first cold room was reviewed and the identified deficiency was addressed in the warehouse by the submitted CAPA.
12. Personnel	Procedures for training SOP was reviewed and found accepted. Initial, continued and on job training were conducted. The training records on the implementation of GSDP, 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.
14. Activities and operation	Activities and operations were performed in accordance with documented procedures according to activities SOP. It was reviewed and found accepted. -Receiving: -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. -Storage:



	-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. -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 vehicles were checked for cleaning before loading.
15. Outsourced activities	All activity relating to the storage and distribution of a medical product that is delegated to another person or entity performed by the appropriately authorized parties, in accordance with national legislation and the terms of a written contract, with SOP 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, (مخزن (ديوان المديرية-ح الرئيسة) (الطعوم بمديرية الشئون الصحية بشمال سيناء) Located at (ديوان المديرية-ح الرئيسة), 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



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	9 https://www.who.int/publications/m/item/trs961-Annex9-modelguidanceforstoragettransport • 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
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