EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the site	**مخزن** طعوم مديرية الشئون الصحية بالبحر الأحمر
Inspected site	
Address of inspected site	الدهار-مستشفي الغردقة العام-مدينة الغردقة-محافظة البحر الأحمر
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 medical products, vaccinations, 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 (QMS)	The roles and responsibilities of personnel were defined and understood by all individuals involved. These were documented through written job descriptions, and there was an authorized organizational chart in place to indicate the responsibilities and interrelationships of personnel within the organization. This chart ensures that each person's duties are clearly understood and aligns with the quality objectives of the company was reviewed. SOPs were reviewed and found accepted.
2. Quality risk management (QRM)	The company conducts quality risk management (QRM) based on an established risk management procedure SOP It was reviewed and accepted as this procedure outlined the process for assessing, controlling, communicating, and reviewing risks at every stage of the supply chain. Risk assessment for storing products in the refrigerators was reviewed and found accepted.
3. Management Review	The management review SOP focuses on reviewing the overall effectiveness of the quality system. There is available minutes and related documentation from management review meetings, It was reviewed and accepted.
4. Complaints	Complaints are handled according to SOP to ensure proper investigation and corrective actions are taken if needed. Each complaint is evaluated to determine if it could indicate a wider issue affecting multiple batches of the product. It was reviewed and accepted
5. Returned goods.	SOP was reviewed and found that all returned products were inspected and segregated in the secured area specified, it was reviewed and found accepted.
6. Recalls	Recalled products were handled according to SOP was reviewed and accepted. the last mock recall was performed and the results shows that the recall system was effective and capable of ensuring product traceability.
7. Self-inspection	SOP was reviewed and found accepted as criteria for the team selection was mentioned. The last self-inspection and its report and related CAPAs was reviewed and 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	Written procedures for stock control and product rotation are in place to ensure that products are stored properly and used before their expiration dates. This system helps maintain product quality by ensuring that older stock is used before newer stock. was reviewed and accepted
10. Equipment	Equipment used with appropriate design, and suitably located for its intended use and it was properly maintained. The data loggers used for monitoring of temperature and humidity were calibrated, The warehouse computer system is (UPA), and testing of the system showed that it is capable of fulfilling its function, the computer system used for controlling and monitoring storage and distribution of goods was reviewed and found accepted.
11. Qualification and validation	Thermal mapping study for cold store was reviewed and accepted as there was a diagram indicating the area mapped and challenge tests were performed. Qualification and validation was reviewed and found accepted. The identified deficiency was addressed by the warehouse in the submitted CAPA.
12. Personnel	The company employs had a sufficient number of qualified personnel to carry out all necessary activities. Standard operating procedures for training, and record for training was reviewed. there is a written training program including initial & continued training, cover the requirements of GSDP guidelines, training and explanation of SOPs were also provided and it was reviewed and found accepted. Regarding Personnel qualification, responsibilities, hygien, there were safety procedures in place relating to all relevant personnel and property, environmental protection and product integrity. There is a written procedures cover health, hygiene and the clothing of personnel was reviewed and accepted.
13. Documentation	There were standard operating procedures for documents. It was

	reviewed and found accepted as Document control was handled according to established procedures, ensuring that documents were reviewed and updated regularly.
14. Activities and operation	All key activities, including the receiving and handling of incoming shipment in wholesales warehouses (by automated method. SOP of Dispatch of drugs and transportation of products, and storage of products was reviewed. There was a sanitation program available indicating frequency of cleaning and methods to be used to clean the storage area. There is pest control program. There was a written procedure for fire control including prevention of fire, fire detection & fire drills. All documents were reviewed and found accepted. Vehicles were suitable for their purpose, with sufficient space and appropriately equipped to protect medical products The identified deficiency was addressed by the warehouse in the submitted CAPA.
15. Outsourced activities	Any activity relating to the storage and distribution of a medical product that is delegated to another person or entity was performed according to the SOP.
16. Substandard and falsified products	Written procedures for falsified products are in place, 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** الدهار-مستشفي الغردقة العام-مدينة الغردقة-محافظة البحر Located at (طعوم مديرية الشئون الصحية بالبحر الأحمر الأحمر), 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