EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the site	مخزن الطعوم والامصال مديرية الشئون الصحية بقنا
Inspected site	
Address of inspected site	محافظة قنا – مدينة قنا – ديوان مديرية الشئون الصحية بقنا امام مستشفى الصدر
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.
Assessment of the Site Master File (SMF) if present	There was an SMF for the warehouse was reviewed and maintained in accordance with the applicable requirements.
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	The warehouse operates under a defined quality management

(QMS)	system to ensure compliance with applicable regulations and quality standards. The warehouse conducts (QMS) SOP of quality manual was reviewed. There were SOPs for major activities of the warehouse. there was an authorized organizational chart in place to indicate the responsibilities and Interrelationships of personnel within the organization Job description were reviewed and found accepted
2. Quality risk management (QRM)	- The company conducts Quality Risk Management (QRM) based on established risk knowledge with SOP. Regarding Identification, assessment, control, communication and review of risks to the quality of the medicinal products at all stages in the supply chain and procedures were dedicated to minimizing or eliminating the risk. The risk study was reviewed and accepted.
3. Management Review	There was a system for periodic management review according to procedures. Including key discussion points and recommendations by using KPIs and opportunities for continual improvement, last minute was held on time, the recommendations and action points on form was reviewed and accepted.
4. Complaints	Managing and recording complaints according to SOP that ensure proper investigation and corrective actions were taken if needed with defined time frame of response. It was reviewed and accepted.
5. Returned goods.	Returned products were separated and the system of returned products conducts in SOP. Also, handling of expired products were done according to the approved procedures.
6. Recalls	Regarding a system to handle recalls there was SOP. All recalled products secured, segregated and stored in appropriate conditions. Mock recall was carried out and the effectiveness checked annually was reviewed and found accepted
7. Self-inspection	SOP for self-inspection was reviewed. Internal audits were conducted according to the company's procedures, annual schedule plan form. Self-inspection team was found to be independent, trained and qualified. SOP for Corrective and preventive measures was reviewed and accepted.
8. Premises	Premises were suitably located, designed, constructed and maintained, to ensure appropriate operations such as storage, cleaning, and picking of medical products. -There was a suitable air conditioning system to ensure proper storage conditions in the warehouse.

	- There were calibrated data-loggers in the warehouse, there were rodent traps and insect killers.
9. Stock control and rotation	Written procedures for stock control and product rotation were in place, record for stock reconciliation was reviewed and accepted.
10. Equipment	Regular backups of computer system (UPA) which capable to achieving the desired output, results & met the requirements to ensure traceability and confidence in the supply chain, access levels were reviewed and all equipment in the warehouse The identified deficiency was resolved following the implementation of the submitted CAPA
11. Qualification and validation	There was SOP for Qualification and Validation was reviewed - The cold room thermal study was performed The identified deficiency was addressed by the warehouse in the submitted CAPA.
12. Personnel	There was an adequate number of personnel, they had appropriate educational qualifications and experience, procedure cover safety, health, hygiene and the clothing of personnel Was reviewed and accepted. Training procedure and plan for annual training was reviewed and accepted.
13. Documentation	Documentation was well-structured, with written procedures in place for all operations, records are maintained for the back-up of data, the overwriting and correction following ALCOA+ system.
14. Activities and operation	**Receiving and dispatching:** - Regarding a system for operations and activities in the company has SOP was reviewed and the identified deficiency was resolved following the implementation of the submitted CAPA -**Storage:** - Regarding a system for Storage. The company has SOP for storage of vaccines in cold room and SOP for storage of vaccines in icelined, and SOP for storage of vaccines in Freezers. They were reviewed and accepted. - There was appropriate control to prevent and handle spillage and breakage it was reviewed and accepted. - Procedures for cleaning SOP it was reviewed and

	accepted. - There was a pest control program in place with SOP and pest killers were checked constantly. It was reviewed and accepted. - There was a written procedure for fire control including prevention of fire it was reviewed and accepted. - Access to the warehouse is restricted to authorized personnel only. **- Distribution and Transport:** - Regarding a system for distribution and transportation handling was reviewed and found accepted.
15. Outsourced activities	Regarding to outsourced activities, SOP was reviewed, and List of service providers was reviewed.
16. Substandard and falsified products	Handling medical products that were suspected to be substandard and/or falsified was done according to the SOP was reviewed and 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 محافظة قنا – مدينة قنا – ديوان مديرية الشئون الصحية) Located at (الطعوم والامصال مديرية الشئون الصحية بقنا بقنا امام مستشفى الصدر), 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