EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the site	**مخزن الطعوم والامصال مديرية الشئون الصحية باسوان**
Inspected site	
Address of inspected site	محافظة اسوان – مدينة اسوان – السيل مطلع الصداقة امام مخزن بيبسى
Inspection details	
Dates of inspection	**22\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 serums and vaccines, no raw material, hazardous or narcotic stored in the site.
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 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, SOPs for major activities of the warehouse, an authorized organizational chart in place to indicate the responsibilities and Interrelationships of personnel within the organization and Job description for Pharmacist manager 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 for storing products 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 on time, the recommendations and action points on form was reviewed and accepted
4. Complaints	System for managing and recording complaints according to SOP that ensure proper investigation and corrective actions are taken if needed with defined time frame of response. It was reviewed and found accepted
5. Returned goods.	Returned products were separated and the system of returned products conducts in SOP. and handling of expired products according to procedures were reviewed and found accepted.
6. Recalls	Regarding a system to handle recalls there was SOP. all recalled products secured, segregated and stored in appropriate conditions. 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	SOP was reviewed. Internal audits are conducted according to the company's procedures, annual schedule plan form. Self-inspection team was found to be independent, trained and qualified, report was reviewed and found accepted. SOP for

	Corrective and preventive measures. It was reviewed and found 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, pest traps and insect killers. The identified deficiency was addressed in the submitted CAPA.
9. Stock control and rotation	Written procedures for stock control and product rotation are in with SOP, record for stock reconciliation, It was reviewed and found accepted. The last stock control and rotation was conducted successfully and properly documented.
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.
11. Qualification and validation	Qualification and Validation has SOP that was reviewed and accepted. There was thermal mapping study for cold room. The identified deficiency was addressed following the implementation of 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, record for training and plan for annual training was reviewed and accepted. - Regarding Personnel qualification, responsibilities, hygiene and number adequacy. It was reviewed and found accepted.
13. Documentation	Documentation was well-structured, with written procedures in place for all operations, SOP was reviewed and found accepted as records were maintained for the back-up of data, ALCOA+ system was considered.
14. Activities and operation	-**<u>Receiving and dispatching</u>:** - Regarding a system for operations and activities in the

	company has SOP It was reviewed and found accepted. -**Storage:** - Regarding a system for Storage. the company has SOP for storage of vaccines in cold room and SOP for storage of vaccines in ice lined, SOP for storage of vaccines in Freezers were reviewed and found accepted. - There was a written procedure for fire control including prevention of fire, fire detection with SOP - The form of fire extinguishers maintenance and the form of Fire alarm system maintenance were reviewed. - Procedures for cleaning SOP. and cleaned constantly in form were reviewed and found accepted. - There was a pest control program in place with SOP. and pest killers were checked constantly in form. - Access to the warehouse is restricted to authorized personnel only, SOP of access control. - Temperature was controlled and monitored at regular intervals for all Cold chain equipment's with SOP with and recorded with form for all cold chain equipment's and form for all cold chain equipment's that contain fridge tag. - SOP for dealing with diffraction. - There was appropriate control to prevent and handle spillage and breakage with SOP. They were reviewed and found accepted. **Distribution and Transport:** - Regarding a system for distribution and transportation handling, the warehouse had SOP. The identified deficiency was addressed following the submitted CAPA.
15. Outsourced activities	Regarding to outsourced activities, It was reviewed and found accepted
16. Substandard and falsified products	Regarding the procedures to assist in identifying and handling medical products that were suspected to be substandard and/or falsified the warehouse had SOP, It 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 الطعوم والامصال مديرية الشئون الصحية باسوان)**
- Located at (محافظة اسوان – مدينة اسوان – السيل مطلع الصداقة امام مخزن بيبسى), 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 • 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