EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the site	مخزن امصال مديرية الصحة
Inspected site	
Address of inspected site	دمنهور ديوان مديريه الصحة اول الكوبري العلوي- محافظة البحيرة
Inspection details	
Dates of inspection	26/1/2026
Type of inspection	This is a 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	Vaccine warehouse located in Damanhour, Beside the high bridge is working in the distribution of vaccines, no raw material, 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 (QMS)	There was designed, documented and correctly implemented quality management system to ensure that the quality of the products is maintained throughout supply chain, SOP of SOP. There was a written quality manual. The roles and responsibilities of personnel were clearly defined and understood by all individuals involved. These were documented through written job descriptions form and there was an authorized organizational chart in place to indicate the responsibilities and interrelationships of personnel within the organization form. SOPs were reviewed and found accepted
2. Quality risk management (QRM)	There was a system to assess, control, communicate and review risks identified at all stages in the supply chain, the SOP. Specified a risk team to manage risk process. The evaluation of risk based on scientific knowledge. Risk assessments were reviewed and found accepted.
3. Management Review	The management review process SOP indicates periodic management reviews, opportunities for continual improvement and follow-up on recommendations from previous meetings. Minute and related documentation were reviewed and found accepted.
4. Complaints	There was a written procedure for the handling of complaints, SOP. Complaints procedures differentiated between complaints about the product and those related to the service offered by the warehouse. It was reviewed and found accepted.
5. Returned goods.	Written SOP was in place for handling returned products was reviewed and found accepted. Returned invoice was reviewed and found accepted as returned goods were assessed for quality issues and stored in a secure location while decisions were made regarding their further use or destruction. Examination of the returned goods, with decisions taken by suitably qualified, experienced and authorized persons.
6. Recalls	Regarding to handling of recalled products, it was done according to SOP There was mock recall was performed successfully and the results shows that the recall system was effective and capable of ensuring product traceability found accepted.
7. Self-inspection	Regarding to self-inspection, the activity was done according to SOP Last self-audit was on time. self-inspection Plan was

	available; they were reviewed and found accepted.
8. Premises	Premises had enough lighting and ventilation, There were 3 air conditions,3 air curtains,2 generator,2 cold rooms and 5 freezer, There was a pest control program, Pest traps and insect killers were available, a fire system was in place, ,records for cleaning and monitoring temperature were available and was reviewed and found accepted, There were efficient security.
9. Stock control and rotation	Regarding to stock control, it was found to be done annually, it was done according to SOP and Last record they were reviewed and found accepted.
10. Equipment	Regarding to equipment, there was a list of equipment used with appropriate design and suitably located for intended use, Coding SOP, Last maintenance of fire equipment was done, Alarm of cold rooms were available, Last calibration for fridge tag for cold rooms was done, SOP of calibration, U-P-A computer system used traceability was done, The identified deficiency was addressed by the warehouse by the submitted CAPA.
11. Qualification and validation	Regarding to the scope of qualifications and validation, SOP available, Cold rooms thermal mapping protocol, The identified deficiency was addressed by the warehouse in the submitted CAPA.
12. Personnel	Regarding to personnel, sufficient number was available, and they received initial and continued training according to written SOP . Training Plan for2026 was available, Last training record was Reviewed concerning GSDP requirements, Safety was ensured according to SOP, Personal hygiene was handled according to SOP, they were reviewed and found accepted
13. Documentation	Documentation SOP was reviewed and found accepted as Written procedures for the preparation, review, approval, use of and control of all documents relating to the policies and activities were in place
14. Activities and operation	**Receiving** Receiving was done according to SOP. Receiving form concerning vehicle was reviewed, Receiving was done by the warehouse vehicles, they were reviewed and found accepted. **Storage** Storage was done according to SOP, Handling spillage was done according to SOP, Storage sensitive products was done according to SOP, Cleaning was done according to SOP, Monitoring

	temperature was done according to SOP, they were reviewed and found accepted. **Dispatch** Dispatch was done according to SOP, it was reviewed and found accepted.
15. Outsourced activities	There were no activities relating to the storage and distribution of medical product that was delegated to another person or entity. SOP was in place was reviewed and found accepted.
16. Substandard and falsified products	Handling substandard and falsified products 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 امصال مديرية الصحة) Located at (دمنهور ديوان مديريه الصحة اول الكوبري العلوي- محافظة البحيرة), 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