EDA Public Inspection Report (GSDP)

Part 1	**General information**
Inspected site details	
warehouse information	
Name of the site	RAMCO Pharm for import, export and commercial agencies.
Inspected site	
Address of inspected site	5th industrial zone, no.2A, 6th of October, Egypt.
Inspection details	
Dates of inspection	25 /09/2023
Type of inspection	***local, planned, and announced***
Scope	
Scope	This is a routine inspection conducted over warehouse within the execution of the 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	RAMCO Pharm for import, export and commercial agencies was one of the warehouses in Egypt that located in 5th industrial zone, no.2A, 6th of October, Giza Governorate with licenses no. 57 and date of issuing of license of the site was 2018.
Assessment of the Site Master File (SMF) if present	RAMCO site master file has been assessed and found accepted.
Abbreviations	
EDA	Egyptian Drug Authority
GSDP	Good Storage and Distribution Practice
WHO	World Health Organization
BPI	Biological Products Inspection Administration
CAPA	Corrective and Preventive Action
SOPs	Standard Operating Procedures
QMS	Quality Management System
QRM	Quality Risk Management
Part 2	**Brief summary of the findings and comments**

1. Quality management system (QMS)	The roles and responsibilities were clearly defined and understood by the individuals concerned, and recorded as written job descriptions and there was an authorized organizational chart to indicate the responsibility, authority and interrelationships of personnel. There was written quality manual that was describing the overall intentions and requirements regarding quality as quality policy objective & scope, authority and responsibilities.
2. Quality risk management (QRM)	SOP of risk management system was reviewed and was coping with current GSDP requirements. Risk assessment report to evaluate the controls and address opportunities for Ramco pharm warehouse was revised and found accepted. It was identifying and managing many risks related to patient, operators, products, processes and environment. The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection
3. Management Review	Procedure for management review was reviewed and found acceptable. It was mentioning review effectiveness of training and training programs, review of suppliers, review of subcontractors and other reviews. There was management review meeting minutes including review of quality policy and objectives.
4. Complaints	Handling of market complaint SOP was reviewed and found accepted in the case of a complaint about the quality of a medical product or its packaging, the original manufacturer and/or marketing authorization holder should be informed, all complaints should be recorded and appropriately investigated. The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection
5. Returned goods.	Regarding to handle of returned goods. The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection
6. Recalls	The company had in place a system for promptly managing recalls in accordance with procedure was reviewed and found accepted in mentioning that the original manufacturer and/or marketing authorization holder, or other relevant contract party, informed in the event of a recall and information on a recall would be shared with the appropriate national or regional regulatory authority. The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection

7. Self-inspection	Procedures for self -inspection management was reviewed and found accepted as it included the team conducting the inspection were free from bias and individual members were appropriate knowledge and experience and necessary CAPAs were taken and their effectiveness reviewed within a defined time frame The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection
8. Premises	Generally, Premises were suitably located, designed, constructed and maintained, to ensure appropriate operations such as receiving, storage, picking, packing and dispatch of medical products. Procedures for cleaning was revised and found accepted. The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection
9. Stock control and rotation	Periodic stock reconciliation was performed at defined intervals, by comparing the actual and recorded stock in accordance with written procedure. Records of stock levels for medical products in store were maintained in electronic format and paper format. The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection
10. Equipment	The equipment used for environmental monitoring were used with appropriate design, and suitably located for their intended use.
11. Qualification and validation	The site had in place procedures for performing qualification/validation of facilities, equipment, and processes, the uniformity of the temperature across the cold rooms and storage areas was studied. Thermal validation protocol for finished product warehouse. Thermal validation protocol for finished product warehouse, thermal validation study for cold room(unit-2) and thermal validation study for cold room(unit-1) were reviewed and found accepted. The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection
12. Personnel	Personnel were receiving initial and continued training, Procedures for training was reviewed and found accepted. Training plan was revised. The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection
13. Documentation	In general, documents were regularly reviewed and kept up to date. However, some weaknesses in the documentation were observed and these need to be improved. The identified deficiency was addressed by the warehouse in the submitted CAPA and were verified during the follow up inspection

14. Activities and operation	Activities and operations were performed in accordance with documented procedures. **Receipt and Storage:** Activities relating to receiving and Storage processes were carried out according to written Procedures. SOP named (monitoring of temperature &relative humidity), SOP of cold stores operation, and SOP of product receiving were reviewed and found accepted. **Distribution and transport:** Medical products were transported in accordance with written procedures for transportation in RAMCO was reviewed and found accepted. **Dispatch:** Activities relating to dispatch processes were carried out according to written Procedure named (distribution of finished goods from warehouse), was reviewed and found acceptable.
15. Outsourced activities	There wasn't any activity relating to the storage and distribution of a medical product that is delegated to another person or entity.
16. Substandard and falsified products	The quality system was including procedures to assist in identifying and handling medical products that were suspected to be substandard and/or falsified was revised 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, (RAMCO Pharm for import, export and commercial agencies.) Located at (5th industrial zone, no.2A, 6th of October, Egypt.), 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