THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

SEVIER EGYPT INDUSTRIES LTD, EGYPT
PUBLIC GMP INSPECTION REPORT

March, 2025

General information about the company

Manufacturers details	
Name of manufacturer	Sevier Egypt Industries LTD
Corporate address of manufacturer	1st industrial zone, Plot No. 37, and 2nd Industrial Zone, Plot No.184, 185, 186, 187 and 188, 6th of October City, Giza, Egypt Tel: 00(202) 382 00012 Email: Sei.info@servier.com
Inspected site	
Name & address of inspected manufacturing site if different from that given above	Same as above
Unit/ block/ workshop number	Les Acacia site was located in 1st industrial zone, Plot No. 37 industrial zone (for manufacturing of bulk) Les Palmiers site located in the 2nd Industrial Zone, Plot No.184, 185, 186, 187 and 188, 6th October, Giza, Egypt. (for warehousing of raw materials and finished products, receiving of raw materials, sampling, dispensing, packaging and chemical and microbiological testing)
Inspection details	
Date of inspection	7th - 8th February, 2024
Type of inspection	Renewal GMP Inspection
Introduction	
General information about the company and site	The facility was founded in December 1992 while production activities started in 1994. It is one of the affiliates of Les Laboratories SERVIER –FRANCE. There are two sites with different activities within Servier Egypt; Les

	Acacias site engaged in manufacturing of bulk products and, Les Palmiers site engaged with warehousing, packaging and dispensing operations Facility had a valid manufacturing license issued on 6/7/2022 by Egyptian Drug Authority (EDA) with a serial number 0051/2022
History	The unit has been inspected and approved by EDA and issued Good Manufacturing Practices (GMP) Certificate number P-1352/2023 issued on 30th October 2023 and expiring on 30th March 2025. it has also been approved by other regulatory authorities such as; a. Yemen Health Authorities (2019) b. Pharmacy and Poison Board, Kenya (2022) c. National Drug Authority, Uganda, 2022
Brief report of the activities undertaken	
Areas inspected	The inspection focused on the General OSD (tablets and Capsules) manufacturing lines starting with inspection of external surroundings, utilities, production areas and quality control for the Les Acacias site and later inspection of materials receiving, sampling, packaging operations and quality control laboratory at the Les Palmiers site.
Restrictions	None
Out of scope	
Production lines inspected by TMDA	General Oral Solid Dosage formulations in form of tablets and capsules
Abbreviations	**Meaning**

AHU	Air Handling Unity
BMS	Building material system
FPP	Finished Pharmaceutical Products
GMP	Good Manufacturing Practices
NaoH	Sodium Hydroxide
RO	Raw Water
OSD	Oral solid Dosage
QA	Quality Assurance
QC	Quality Control
SMBS	Sodium metabisulphite

Part 2: Brief summary of the findings and comments

The surroundings of the facility were inspected followed by tracing the logical flow of production from incoming raw material to the finished goods warehouses. During inspection various relevant working documents were evaluated and technical staffs interviewed on various aspect of GMP relevant to their work

1. Personnel

The facility had an adequate number of personnel. The qualification and experience of key personnel were verified and found appropriate for the functions they were carrying out. The Head of Quality Assurance (QA) was responsible for overall quality issues including review of documentation and ensuring the processes are implemented as per the requirements. QC Manager and Production Managers were independent from each other. Generally, Production Head was responsible for all production activities and Quality Head was responsible for all quality control activities including release of FPP to market.

All employees received initial and frequent refresher training regarding the principles of GMP. Training records for employees working in the microbiology laboratory were retrieved and found well documented.

All employees were supposed to undergo pre-placement and periodical health check-up. Health screening was conducted for employees interacting directly with the product (e.g Production/Quality Control).

2. Premises

a. Layout and Design

The facility consisted of two premises; one for manufacturing of bulk (Les Acacias site) and the other for warehousing of raw materials and finished products, receiving of raw materials, sampling, dispensing, packaging and chemical and microbiological testing. These were separated by a distance of 1km. In the Les Acacia site, the walls and floors were observed to be smooth and was constructed to coved corners.

b. Sanitation and Hygiene

Both premises had provisions for change rooms and areas with cleanliness level appropriate for products to be manufactured. Facility personnel were gowning as per Procedure. It prevented operators to cross from one process room to another clean area or another process room with different product, unless the PPE was replaced by a new one. In all change rooms pictorial diagrams of steps to be followed in clothes changing were available.

3. Production

Materials which had been received, sampled and dispensed at the Palmiers site were received at Les Acacias site as per procedure. The facility had only OSD line (tablets and capsules) comprising of one granulation room, 4 compression rooms, and 3 coating machines. During production, monitoring of differential pressures and relative humidity for rooms and corridor were performed by BMS and records maintained.

Line clearance was performed before production and all activities recorded in the BMR as evidenced for Buscopan Batch No. 33407 which was found at compression stage. In-process quality control tests such as weight variation, disintegration, hardness, friability, thickness, weight gain (coated tablets) was conducted for tablets and tests such as weight variation, thickness, dissolution, capsule length (lock length) and appearance were carried out during production of capsules at regular intervals as provided in the BMR. After production, proper cleaning was performed as per established procedures, records were verified.

4. Quality Control

Quality control laboratory was equipped with adequate number of qualified instruments which were found to bear valid calibration sticker labels or appropriate status labels. Analytical procedures used for routine monitoring of materials and finished products were of current pharmacopeial methods, and where applicable validated in-house methods. There were appropriately authorized and dated specifications for raw materials, packaging materials and finished products. There were also authorized specifications for intermediates, water, solvents and reagents.

The facility had procedure for retaining and destruction of raw Material and finished products samples. Retained samples of raw materials were required to be kept for a minimum period of 2 years past their expiration date and 1-year post expiry for finished products.

5. Equipment

Equipment was found with status labels according to the activity, cleaning labels were affixed on equipment and identity of the previous product was indicated. Equipment was qualified and preventive maintenance was performed at regular intervals as per planned schedule. Manufacturing equipment was generally suited for their intended purposes, equipment log books were also in place. Equipment was calibrated at a predetermined frequency and records maintained.

6. Purified water System

The facility used City water as feed water for the water treatment plant. The purification system composed of a series of stages to include filtration by sand filter, chlorination, dichlorination by SMBS then filtration through a 10µm filter. Water was then treated with NaOH, filtered through 5µm then to the two stage RO system followed by further filtration through filtration by 5µm filter before storage. During the process online monitoring for temperature, conductivity, flow rate and pressure were performed.

Sanitization of the water treatment plant was conducted by hot water once in every month as supported by records.

7. Heating, Ventilation and Air Conditioning

There was a total of 6 AHUs for the Les Palmiers site and 11 AHUs for Les Acacias Site to supply filtered air to production, storage and quality control areas. AHUs were composed of filters with appropriate size which were monitored through magnehelic gauges with sensors linked to the Building Management System (BMS). Air was supplied to provide high pressure in the corridor of production compared to the pressure of the production cubicles. AHUs were maintained and no issue was observed in the HVAC system.

8. Document Review

Documents were reviewed and found prepared, authorized and distributed to vantage areas as per GMP requirements. They were properly adhered and records were maintained

Part 3: Conclusion

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, **Servier Egypt Industries LTD, Les Acacia site, 1st industrial zone, Plot No. 37 industrial zone, and Les Palmiers, 2nd Industrial Zone, Plot No.184, 185, 186, 187 and 188, 6th October, Guiza, Egypt** was considered to be operating at an acceptable level of compliance with TMDA GMP Guidelines for Human Medicines for production of **general oral solid dosage forms (i.e. tablets and capsules).**

This TRIP will remain valid for three (3) years from the date of approval for GMP compliance provided that the outcome of any inspection conducted during this period is positive

Part 4: References

1. Sevier Egypt Industries Ltd (2024), 6th of October City, Giza, Egypt GMP Inspection Report
2. TMDA (2023) Guidelines for Good Manufacturing Practices Inspection of Human Medicinal Products Manufacturing Facilities, First Edition
3. TMDA Good Manufacturing Practices Manual and SOPs, Tanzania Medicines and Medical Devices Authority Dar-es-Salaam, Tanzania. GMP Inspection Report forms No. TMDA/DMC/MCIE/F/036 Rev #: 02
4. TMDA (2019) Tanzania Medicines and Medical Devices Act, Cap 219
5. Servier Pharmaceutical Industries Site Master File (SMF), SMF/SEI-12
6. TMDA (2018) Good Manufacturing Practices Enforcement Regulations, GN 295