Serial :00014/2025

Licensing inspection report summary

Part 1: Manufacturer details:

- **Manufacturer name**: National Company for maize products- sorbitol pharma factory.
- **Manufacturer address**: plot no. (3/1)" except ambergris no. 9 which is rented to Cairo 3A Company for distribution " industrial zone A1 – 10th of Ramadan City -Alsharqia.
- **New manufacturer**: √ **- licensed manufacturer**: ×
- **Licensing inspection date**: 5/2/2025
- **Date of previously licensing inspections**: ----------

Part 2: Scope of licensing inspection

Production line of Raw material (Pharmaceutical Sorbitol)

Part 3: Brief description about previously licensed production lines (in case of licensed factory)

National Company for maize products- sorbitol pharma factory is a new factory for production of raw material (Pharmaceutical Sorbitol).

Part 4: Summary of the findings and comments

- The opening meeting started with a presentation explaining the manufacturer activities in details from the authorized person who represented the factory layout including the different flows as personnel, material, waste, areas classification and differential pressure.
- Then a tour for the facility was conducted to involve production area, water station, and microbiological and chemical laboratories.
- After the tour, the required documents for area and equipment qualification and all the required documents were reviewed.
- A close meeting was held by the committee members to decide the final conclusion and the committee decision was taken.
- Wrap up meeting was held to inform the factory representatives with the committee final decision

Part 5: Areas inspected

Preparation area, filling area, packaging areas, AHUs, laboratories, warehouse, water treatment station, compressed air generator, all supplies.

Part 6: Description

1- Preparation area, filling area, packaging area, all supplies, water treatment station

The facility shows compliance to GMP guidelines regarding:

- Suitable layout showing logic process flow.
- The factory premises shows adequate spaces.
- Classification and differential pressure were revised and complying.
- Suitable equipment used in manufacturing process.
- Facility was kept clean and had adequate lighting, ventilation, and environmental control.
- Area and equipment documentations and qualification were revised.
- Area supplies qualifications were revised and found complying.

2- Warehouse

- Adequate spaces and segregation of quarantine and released for raw materials, finished products, packaging materials was present.

Warehouses were found in a good cleanliness state with adequate lighting, ventilation.

3- Laboratories

- Laboratories premises layout was designed to suit the operations to be carried out.
- Appropriate calibrated equipment was present.
- Sufficient space was provided

Part7: References

- As per the law 151 for year 2019 of "promulgating law establishing the Egyptian authority for unified procurement, medical supply and technology management (AUPP) and Egyptian drug Authority (EDA) article 17 which stated "EDA shall exercise all regulatory …...according to international standards".
- Also, as per prime minister degree no.777 for year 2020 article 17 which stated "…EDA adoption of standards and requirements of world health organization for the norms and requirements of good manufacturing practice (GMP).
- And all with taking into considerations the WHO references listed in the following link:

- https://www.edaegypt.gov.eg/ar/%D8%A7%D9%84%D9%82%D9%88%D8%A7%D9%86%D9%8A%D9%86-%D9%88%D8%A7%D9%84%D9%82%D8%B1%D8%A7%D8%B1%D8%A7%D8%AA-%D9%88%D8%A7%D9%84%D9%82%D9%88%D8%A7%D8%B9%D8%AF-%D8%A7%D9%84%D9%85%D9%86%D8%B8%D9%85%D8%A9-%D9%88-%D8%A7%D9%84%D8%A5%D8%B4%D8%B9%D8%A7%D8%B1%D8%A7%D8%AA/%D8%A7%D9%84%D9%85%D8%AF%D9%88%D9%86%D8%A7%D8%AA-%D8%A7%D9%84%D9%85%D8%B1%D8%AC%D8%B9%D9%8A%D8%A9/

Part 8: Conclusion & The licensing inspection committee final decision.

Conclusion:

- Based on the areas inspected, the people met, and the documents reviewed, there was an acceptable level of compliance regarding: Production Areas, Equipment, warehouses, laboratories reviewed documents.
- The comments observed during the licensing inspection were listed in the complete licensing inspection report and were addressed by the manufacturer & should be fulfilled before starting production from inspector of administration of inspection of pharmaceutical products factories for human, veterinary, herbal and disinfectants.

The licensing inspection committee final decision.

Granting the license