Serial :0017/2025

Licensing inspection report summary

Part 1: Manufacturer details:

1. **Manufacturer name**: El-Nile Co. for pharmaceuticals & chemical industries.
2. **Manufacturer address:** El-Sawah Street -El-Amirya - Cairo.
3. **New manufacturer**: × **- licensed manufacturer**: √
4. **Licensing inspection date**: 19/10/2025
5. **Date of previously licensing inspection:** 13/10/2025

Part 2: Scope of licensing inspection

Upgrade Solid dosage forms Production area of (Tablets, capsules and Granules for oral suspension filled in bottles).

Part 3: Brief description about previously licensed production lines

- **General dosage forms:**
  - ✓ **Non sterile products:**
    1. **Solid dosage form:** Tablets (coated , uncoated) , Hard gelatin capsules, Effervescent & non effervescent granules , Granules for oral suspension .
    2. **Liquid dosage form:** Syrup , suspension , emulsion, oral & nasal drops.
    3. **Semisolid dosage form:** Ointment, cream , gel , Suppositories & pessaries.
  - ✓ **Sterile products:**
    4. Small volume parenteral (S.V.P.) , aseptic filling include:solution for injection , nebulizer solution for inhalation & WFI.
    5. Large volume parenteral (L.V.P.) (terminal sterilization).
    6. Three lines of ampoule (liquid & lyophilized)liquid (aseptic filling &terminal sterilization).
- **Hormonal dosage form:**
  - ✓ **Sterile Products:**
    7. ampoule (liquid &lyophilized)
- **Disinfectant building:**
  12.Two lines of povidone iodine antiseptic (Gargles - shampoo - douches - disinfectant solution)
- **Cosmetics:**
  13.Lotion
- **Bio-technology area : (suspended area)**
  - ✓ **Sterile Products:**
    10.lyophilized powder
    11.vial (solution)

Part 4: Summary of The Findings and Comments

The opening meeting started with a presentation explaining the scope of licensing inspection of Upgrade Solid dosage forms Production area of (Tablets, capsules and Granules for oral suspension filled in bottles) from the production manager who represented the purpose of the visit.

-Then a tour for the facility was conducted to involve production area, water station, AHUs and microbiological and chemical laboratories..

-After the tour, the required documents for area and equipment qualification 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, water treatment station and laboratories.

Part 6: Description

1- Preparation area, filling area, packaging area, all utilities serve area.

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 were found 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- Laboratories

- Laboratories premises layout was designed to suit the operations to be carried out.
- Appropriate calibrated equipment was present.
- Sufficient space was provided
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Part 7: 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 minster 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 inspected machines and the documents reviewed, an acceptable level of compliance with WHO GMP guidelines was shown regarding Production areas, Equipment, Utilities, reviewed documents.

The licensing inspection committee final decision.

Granting the license and fulfillment of minor comments will be followed and monitored by The General Administration of Factories Inspection.