Serial :00025/2025

Licensing inspection report summary

Part 1: Manufacturer details:

- **Manufacturer name:** Egyptian company for production of vaccines, sera & drugs (EGYVAC)
- **Manufacturer address:** 51 Wezaret El Zeraa St. – Agouza – Giza
- **New manufacturer**: ×
- **licensed manufacturer**: √
- **Licensing inspection date**: 15/10/2025
- **Date of previously licensing inspections:** -

Part 2: Scope of licensing inspection

Adding of cold rooms inside the factory.

Part 3: Brief description about previously licensed production lines

Vaccines, Sera & Biological products:

1- Building for Production of Concentrate Tetanus Toxoid (intermediate product).
2- Building of Diphtheria & Pertussis.
   - Concentrates Area: Concentrate Diphtheria Toxoid, Concentrate Pertussis, Concentrate cholera & Concentrate Typhoid.
   - Vaccines Mixing Area.
3- Building no.1 Production of vaccines & sera - filling & packaging of liquid biological product "insulin" in glass vials - oral drops in plastic containers.
4- Building no.2 Production of biological product "insulin" in glass vials - filling & packaging of liquid & lyophilized vaccines & sera in glass vials - production of Tuberculin product.
5- Building no. 60 Production of vaccines and sera (vial & ampoule combi-line) - filling of water for injection in glass ampoules.

Part 4: Summary of The Findings and Comments

- The opening meeting started with a presentation explaining the scope of licensing inspection of adding cold rooms inside the factory.
- Then a tour for the facility was conducted to the cold rooms
- After the tour qualifications 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

Cold area (1), New cold area, Cold area (3), Cold area (4), Cold area (5), Cold area (6), Cold area (7), Veterinary company cold area, Research cold room & Media cold room.

Part 6: Description

Adding of cold areas shows compliance to GMP guidelines regarding:

- Suitable layout, qualifications were revised.
- cold rooms were kept with adequate lighting, ventilation.

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 areas inspected, the people met, and the documents reviewed, there was an acceptable level of compliance.

The licensing inspection committee final decision.

Granting the license