



Serial :0002/2025

### Licensing inspection report summary

#### **Part 1: Manufacturer details:**

- 1- Manufacturer name: Egyptian company for production of vaccines, sera & drugs (EGYVAC)
- 2 -Manufacturer address: 51 Wezaret El Zeraa St. – Agouza – Giza - Egypt.
- 3- New manufacturer: × - licensed manufacturer: √
- 4- Licensing inspection date: 27/12/2023 & 1/1/2024
- 5- Date of previously licensing inspections: -----

#### **Part 2: Scope of licensing inspection**

Clarification of previously licensed production lines to issue the Technical License for Operation

#### **Part 3: Brief description about previously licensed production lines**

Sterile Biological Products: Vaccines & Sera – Biological Medicine

#### **Part 4: Summary of The Findings and Comments**

The opening meeting started with presentation explaining the scope of the licensing inspection in presence of the CAO which was clarification of previously licensed production lines in order to issue the Technical License for Operation for the factory.

- A tour for the production lines was conducted.
- A close meeting was held by the committee members to prepare the report that shows the existing production lines to be stated in the Technical License for Operation.
- No critical or major comments were observed

#### **Part 6: Description**

- There was no change in the previously licensed layout
- Suitable equipment used in manufacturing process.
- Facility was kept clean and had adequate lighting, ventilation, and environmental control and shows compliance to GMP.

#### **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 premises and equipment , an acceptable level of compliance with WHO GMP guidelines was shown regarding: Production areas, Equipment & Utilities

### The licensing inspection committee final decision.

Issuing the Technical license of operation