Serial :0001/2025

Licensing inspection report summary

Part 1: Manufacturer details:

1- **Manufacturer name**: Biogeneric Pharma

2 -Manufacturer address: Plot no. 22 - Zone A3 - 10th of Ramadan city - Elsharkya.

3- New manufacturer: √ **- licensed manufacturer**: ×

4-Licensing inspection date: 19/12/2022

5- Date of previously licensing inspections:12/6/2022

Part 2: Scope of licensing inspection

- Licensing new factory for production of Biological products & Vaccines

Part 3: Brief description about the production lines

*****Biological products & vaccines

- Production line of vial (solution, suspension).
- Production line of cartridges – prefilled syringes – vial (solution, suspension) "single use technology" (Combi-line).

Part 4: Summary of The Findings and Comments

The opening meeting started with a presentation explaining the scope of licensing inspection of the factory to license biological products& vaccines production lines which was performed by the factory manager who represented the scope of the visit.

Then a tour for the factory was conducted involving preparation areas, filling rooms and packaging area, premises, warehouses, QC labs & utilities.

- After the tour, 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.
- No critical or major comments were observed

Part 6: Description

- Facility was kept clean and had adequate lighting, ventilation, and environmental control.
- Area and equipment documentations and qualification were revised

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 areas and the reviewed documents, all comments were addressed by the company, corrective action done shows compliance with WHO GMP guidelines

The licensing inspection committee final decision.

Granting the license.