Serial no.:0001/2026

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 – Egypt
3. **Owner company** : Biogeneric pharma factory is a subsidiary of the Mother Company Biogeneric Pharma Co. (S.A.E) which is located in Egypt
4. **Technical License of Operation** : The factory is licensed for manufacturing of biological products and vaccines , which has granted the Technical License of Operation coded (LiHV2022075/0112022) with validity of 7 years ends on 17/5/2033 .
5. **Licensed production lines:**
   - Vial (solution, suspension) “Biological products / Vaccines / Insulin”.
   - Cartridges - prefilled syringes - vial (solution , suspension) “single use technology” (Combi-line) “Biological products / Vaccines / Insulin”.

Part 2: Background

The licensing inspection team is responsible for conducting a pre-inspection review of the factory to ensure that its facilities, buildings, and equipment are suitable for the intended license. This license is specifically required for the production of biological products and vaccines.

The licensing inspection team's review aims to verify that the factory meets all the necessary technical and regulatory standards stated in Part 5 . Once compliance is confirmed, the Technical License of Operation is issued. This license enables the factory to start production.

Following the issuance of the license, the factory's operations are subject to ongoing monitoring and follow-up through regular GMP inspections.

Part 3: Licensing Inspections

3-1 June 2022 licensing inspection

Date:12/6/2022

Scope : Licensing a new factory for production of vaccines and biological products

Description :

The licensing inspection team assess the manufacturing facility across all operational areas which covered the following:

- Production lines: for all manufacturing stages from raw material processing to final product formulation through 2 production lines : for solution, suspension "Biological products / Vaccines / Insulin "
- Filling areas : aseptic filling areas where products are dispensed into their primary containers through 2 filling lines one is combi line to fill product into Cartridges - prefilled syringes – vial and other is for Vial filling using single use technology .
- Packaging areas : secondary packaging (cartons, labels, leaflets)
- Warehouses : storage areas for raw materials, packaging materials, intermediates, finished products, and rejected or returned goods
- Cold rooms : temperature-controlled storage areas ensuring cold chain integrity for heat-sensitive products for vaccines and biologicals
- Quality control (QC) laboratories : microbiological, chemical, and analytical testing facilities responsible for raw material testing, in-process control, and finished product release testing
- Utilities :supporting systems including HVAC (Heating, Ventilation, and Air Conditioning), purified water systems, steam generation, compressed air.

the licensing inspection team reviewed the required documents, including but not limited to: qualification documentation , validation protocols and reports, equipment qualification documents, environmental monitoring data, standard operating procedures (SOPs).

Key Findings and corrective actions to be taken by the manufacturer:

1. Laboratories:

All essential equipment were not found (e.g HPLC , Incubators , autoclaves) Corrective Actions to be taken by Manufacturer:

- purchase for deficient equipment and perform required calibration

2. Equipment and machines Qualification and Validation

- Incomplete qualification (I.Q Installation Qualification and O.Q operational Qualification) documentation of production equipment , filling lines , labelling machine , Sampling LAF Laminar Air Flow , Formulation LAF and visual inspection machine
- Some equipment are not installed yet (Sampling LAF Laminar Air Flow , Formulation LAF)
- There was No validation for the cold rooms in production and warehouse

Corrective Actions to be taken by Manufacturer:

- Execute qualification documentation
- Install all the equipment
- Execute the Cold Rooms validation

3. Utilities: HVAC, Purified Water, Steam, Compressed Air

- HVAC was not completely installed nor validated as there are no Pre , Bag and HEPA filters and differential pressure monitors were not installed across Air Handling Unit
- Purified water system not validated

Corrective Actions to be taken by Manufacturer:

- Complete the Installation and Validation of HVAC system
- Execute water system validation
- Document all utility qualification reports

4. Premises :

Interior finishes of the factory were not completed

Corrective Actions to be taken by Manufacturer:

- Complete all constructions and internal finishes

Compliance level And Conclusion :

Based on the areas inspected and the documents reviewed and considering the findings , all the non - compliances observed during the licensing inspection were listed in the full report and were addressed to the manufacturer .

The decision was that the factory doesn’t comply with the required GMP standards and corrective

action is required to be submitted from the manufacturer and a fulfillment licensing inspection should be conducted to ensure the compliance with the standards stated in Part 5 .

3-2 December 2022 fulfillment licensing inspection

Date:19/12/2022

Scope : Ensuring the fulfillment of the comments of the previously Licensing inspection conducted on 12/6/2022

Description : The licensing inspection process specifically targeted the fulfillment of the comments of the previously Licensing inspection which was conducted on 12/6/2022.

Findings and corrective actions to be taken by the manufacturer:

Regarding the findings previously observed in Laboratories , Equipment , Premises and Utilities the corrective actions that were addressed by the manufacturer were revised from the licensing inspection team and was found fulfilled as the deficient equipment was purchased and calibrated , all the machines were installed and qualified , Purified water system was validated , HVAC qualification was performed but required to be completed .

Compliance level And Conclusion

The outcome of the licensing inspection was absence of critical or major comments which indicates that the facility demonstrated a satisfactory level of GMP compliance across all assessed areas, with no findings that would materially compromise product quality, patient safety, or regulatory conformity.

Minor observation, would typically be addressed through the facility's quality management system during routine operations , that would be fulfilled by the EDA inspectors , thus the licensing inspection team decided to grant the Technical License of Operation to the factory

This Licensing Inspection Report Summary will be revised to reflect any license-related modifications made by the manufacturer.

Part 4: Abbreviations

EDA : Egyptian Drug Authority

GMP : Good Manufacturing Practice

HVAC : Heating, Ventilation, and Air Conditioning

I.Q : Installation Qualification

LAF : Laminar Air Flow

O.Q : Operational Qualification

Q.C: Quality Control

SOPs : Standard Operating Procedures

WHO : World Health Organization

Part 5: 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).

-EDA chairman decree No. (838) of year 2025 Amending Decree No. (119) of year 2022 regarding the formation of the licensing inspection committee

- 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/