Serial no.:0002/2026

Licensing Inspection Report Summary

Part 1: Manufacturer details:

1-Manufacturer name: Egyptian International Pharmaceutical Industries Company-EIPICO (Factory 3).

2-Manufacturer address: Plot no. 49, 50 – first industrial area B1– Tenth of Ramadan city.

3-Owner company : Egyptian International Pharmaceutical Industries Co.- (EIPICO) (S.A.E.)

4-Technical License of Operation : The factory is licensed for manufacturing of Biological Products & Biological Raw Materials , which has granted the Technical License of Operation coded (LiHV2025017/0042025).

5-Licensed production lines:

- Biological Sterile Products (Vial "solution/lyophilized"- Prefilled syringe (PFS)- Cartridge) (Combi line)
- Two production lines of Primary biological raw material (By biotechnology technique)

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 & Biological Raw Materials.

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 November 2025 licensing inspection

Date: 23/11/2025

Scope : Licensing a new factory for production of Biological Products & Biological Raw Materials

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 the production lines: 1-Sterile products (Vial "solution/lyophilized" – Prefilled syringe (PFS) – cartridge) (Combi-line) 2-Primary biological raw material (By biotechnology technique)
- Filling areas: aseptic filling areas where products are dispensed into their primary containers through filling lines one is combi-line to fill products into Cartridges - prefilled syringes – vial and another two filling lines for Biological raw materials.
- Packaging areas: secondary packaging (cartons, labels, leaflets, packages)
- Warehouses: storage areas for raw materials, packaging materials, intermediates, finished products, and rejected or returned goods – all found in a good cleanliness state with adequate lightening & ventilation.
- Cold rooms: temperature-controlled storage areas ensuring cold chain integrity for heat-sensitive products for biologicals
- Quality control (QC) laboratories: microbiological, chemical, and analytical testing facilities responsible for raw material testing, in-process control, and finished product release testing – all found with appropriate calibrated equipment
- Utilities: supporting systems including HVAC (Heating, Ventilation, and Air Conditioning), purified water systems, steam generation, compressed air.
- Documentation: the required documents were reviewed, 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. Warehouses:

- Vacuum for deduster was not available.
- In tools washing room, the compressed air points was not fully installed .

-Corrective Actions to be taken by Manufacturer:

The compressed air points must be fully installed

Vacuum deduster should be present in the receiving area .

2. Laboratories:

- visual inspection test depends on the production machine .

-Corrective Actions to be taken by Manufacturer:

Visual inspection test should be conducted for random samples

3.Production area :

- Δ P between reception at drug product area & filling room is the same pressure
- Non return valve was not present for the drain of machines & tanks in production area
- Electrical port 380 V found in the filling room class B .

-Corrective Actions to be taken by Manufacturer:

- Δ P between reception at drug product area & filling room should be reviewed not to be in the same pressure.
- return valve should be installed for the drain of machines & tanks in production area
- Electrical port 380 V found in the filling room class B should be covered with stainless steel cover.

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

- Some dust & air particles were found in area B in filtration reception room.

-Corrective Actions to be taken by Manufacturer:

Complete cleaning & disinfection should be done for the area prior production .

Compliance level And Conclusion :

Based on the areas inspected and the documents reviewed .

The decision was that the factory demonstrates 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 during routine operations , that would be fulfilled by the EDA inspectors , thus the licensing inspection committee 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

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-

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