Serial :00001/2026

Licensing inspection report summary

Part 1: Manufacturer details:

- **Manufacturer name**: D B K for Pharmaceutical Industries (D B K Pharma)
- **Manufacturer address:** Industrial Zone North Extension Parts No .8 and 11 Block No. 12014 – El Obour City.
- **New manufacturer**: ×
- **licensed manufacturer**: √
- **Licensing inspection date**: 24/12/2025
- **Date of previously licensing inspections:** -

Part 2: Scope of licensing inspection

Adding of two warehouses inside the factory:

A – Primary packaging warehouse.
B- Secondary packaging warehouse

Part 3: Brief description about previously licensed production lines

*General dosage forms include:

- Solid dosage forms include:
  - Tablet (Coated & Uncoated) “Human” & Bolus “Veterinary”
  - Hard Gelatin Capsule “Human”
  - Powder filled in sachets “Human, Veterinary”
  - Powder filled in bottles, Powder filled in jars and Powder filled in metal cans “Veterinary”
- Liquid dosage forms include
  - Syrup-suspension “Human”.
  - Solution for external use “Human”
- Semi Solid dosage forms include Cream "Human – Cosmetics" and Ointment "Human".

Part 4: Summary of The Findings and Comments

- The opening meeting started with a presentation explaining the scope of licensing inspection of adding two warehouses inside the factory.
- Then a tour for the facility was conducted.
- After the tour required documents 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

A – Primary packaging warehouse.

B- Secondary packaging warehouse

Part 6: Description

Adding of two warehouses inside the factory shows compliance to GMP guidelines regarding:
- Suitable layout, required documents were revised.
- warehouses 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