Serial :0001/2023

Licensing inspection report summary

Part 1: Manufacturer details:

- **Manufacturer name**: Beta Pharma for Pharmaceutical & Chemical Industries For its owner Abd Elfatah Mansy Yousef Anany.
- **Manufacturer address**: Parts no. 63 , 64 – Hundred Acres Area – Badr Industrial City.
- **New manufacturer**: √ **- licensed manufacturer** : ×
- **Licensing inspection date**: 2/10/2023
- **Date of previously licensing inspections**: 4/7/2022

Part 2: Scope of licensing inspection

1- Production line of vial (liquid) (aseptic filling & terminal sterilization).
2- Production line of eye drops (liquid) (aseptic filling).

Part 3: Brief description about previously licensed production lines (in case of licensed factory)

- Beta Pharma For Pharmaceutical & Chemical Industries For its owner Abd Elfatah Mansy Yousef Anany is a new factory its production lines as described

Part 4: Summary of The Findings and Comments

- The opening meeting started with a presentation explaining the manufacturer activities in details from the authorized person Site Manager who represented the factory layout including the different flows as personnel, material, waste, areas classification and differential pressure.
- Then a tour for the facility was conducted to involve production areas, as well as service areas, warehouses, and quality control laboratories.
- After the tour, the required documents for area and equipment qualification and all 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.

Part 5: Areas inspected

Preparation area, filling area, packaging areas, all supplies water treatment station, compressed air generator

Part 6: Description

1- "Preparation area, filling area, packaging areas, all supplies water treatment station, compressed air generator"

The facility shows compliance to GMP guidelines regarding:

- suitable layout showing adequate spaces for free logic process flow.
- classification and differential pressure was revised and complying.
- suitable equipment used in manufacturing process.
- facility was kept clean and had adequate lighting, ventilation, and environmental control.
- Area and equipment documentations and qualification were revised.
- Area supplies qualifications was revised and found complying.

2- Warehouse

- Adequate spaces and segregation of quarantine and released for raw materials, finished products was present.

Warehouses were found in a good cleanliness state with adequate lighting, ventilation.

3- Laboratories

- Laboratories premises layout was designed to suit the operations to be carried out.
- Appropriate calibrated equipment were present.
- Sufficient space was provided

Part7: 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

Part 8: Conclusion & The licensing inspection committee final decision

Conclusion:

-Based on the areas inspected, the people met, and the documents reviewed, and considering the findings of the previous licensing inspection, including the observations listed in the previous

licensing Inspection Report, as well as the corrective actions taken were considered to have been conducted at an acceptable level of compliance regarding: Production Areas, Equipment, warehouses, laboratories, utilities, reviewed documents.

- All the non-compliances observed during the licensing inspection were listed in the complete Licensing inspection report and were addressed by the manufacturer to a satisfactory level before issuance the license and publicity of this report.

The licensing inspection committee final decision.

Granting the license and fulfillment of minor comments will be followed and monitored by the general administration of factories inspection.