Serial :0005/2024

Licensing inspection report summary

Part 1: Manufacturer details:

- **Manufacturer name**: Egyphar (2)
- **Manufacturer address :** Part no. 10 - Block 13026 - Industrial Zone A - Obour city - Qalyubia
- **New manufacturer**: × - **licensed manufacturer**: √
- **Licensing inspection date**: 26/2/2024
- **Date of previously licensing inspections**:……..

Part 2: Scope of licensing inspection

Adding production line of small production / pilot batch of solid dosage forms of Tablet (coated & uncoated)

Part 3: Brief description about previously licensed production lines

- **The previously licensed production lines are the following :**
  1- Solid dosage forms include:Coated & uncoated unilayer and bilayer tablets - hard gelatin capsule.
  2- Liquid dosage forms include :syrup - suspension.

Part 4: Summary of the findings and comments

The opening meeting started with a presentation explaining the scope of licensing inspection of adding a new production line of small production / pilot batch of solid dosage forms include Tablets (coated & uncoated) from the site manager who represented the line layout including the different flows as personnel , material ,waste , areas classification and differential pressure .

- Then a tour for the new production line was conducted to involve production areas for preparation , compression and coating of tablet .
- Warehouses and laboratories that serves the new area were previously licensed .
- 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.

- Wrap up meeting was held to inform the factory representatives with the committee final decision

Part 5: Areas inspected

Preparation area, compression and coating of tablet , laboratories.

Part 6: Description

-The new production line of small production / pilot batch of solid dosage forms includes Tablets (coated & uncoated) premises shows compliance to GMP guidelines.

- Suitable layout showing adequate spaces for free logic process flow.
- Classification and Δp were revised and complies to guidelines.
- 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.
- Regarding the prelicensed laboratories the committee members inspected the laboratories and confirm the presence of appropriate calibrated equipment to perform the required tests to the products of the new production line.

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 minister 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 new production line inspected, the people met, and the documents reviewed, an acceptable level of compliance with WHO GMP guidelines was shown regarding : Production Areas , Equipment , Utilities , reviewed documents .

The licensing inspection committee final decision.

Granting the license .