Serial :0011/2024

Licensing inspection report summary

Part 1: Manufacturer details:

- **Manufacturer name:** Orchidia Pharmaceutical Industries
- **Manufacturer address:** Part no. (14, 15) - Block (12011) - north industrial zone extension - El Obour city - Qalubia.
- **New manufacturer**: × - **licensed manufacturer**: √
- **Licensing inspection date**: 19/2/2024
- **Date of previously licensing inspections**:18/12/2023

Part 2: Scope of licensing inspection

Adding production line of eye drops (single unit dose) (BFS)

Part 3: Brief description about previously licensed production lines

Several production lines were licensed: Sterile dosage forms include Eye drops , Eye gel , Eye ointment , contact lenses

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 eye drops (single unit dose) (BFS) in details from the company CEO and the site manager who represented the new production 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, filling and packaging and concentration of extracts and warehouse of herbs.
- Laboratories that serves the new production 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.

Part 5: Areas inspected

Preparation area, filling area, warehouse, packaging

Part 6: Description

- The new production lines of eye drops (single unit dose) (BFS)show compliance to GMP guidelines.

- Suitable layout showing adequate spaces for free logic process flow.
- Classification and Δp were 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

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 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 .