Serial :0006/2024

Licensing inspection report summary

Part 1: Manufacturer details:

- **Manufacturer name**: Migntra Egypt Healthcare Transforming Medicines.
- **Manufacturer address :** Plot no. 15 & 16/4 – Industrial zone A2 – 10th of Ramadan city.
- **New manufacturer**: × - **licensed manufacturer**: √
- **Licensing inspection date**: 7/2/2024
- **Date of previously licensing inspections**:……..

Part 2: Scope of licensing inspection

Adding two production lines of primary raw biological material.

Part 3: Brief description about previously licensed production lines

- 2 production lines were previously licensed which are the following:
  1- Production of biological active pharmaceutical ingredients produced by genetic engineering techniques.
  2- Production of biotechnological pharmaceutical bulk products from mammalian cells was added on 18/9/2013.

Part 4: Summary of the findings and comments

- The opening meeting started with a presentation explaining the scope of licensing inspection of adding two production lines of primary raw biological material in details from the factory representative who represented the two new production lines layout including the different flows as personnel, material, waste, areas classification and differential pressure.
- Then a tour for the two new production lines were conducted to involve production area sampling area, warehouse.
- laboratories that serves the two new production areas was 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 , sampling area, warehouse , laboratories .

Part 6: Description

- The two new production lines of primary raw biological material premises shows 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.
- 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/%D

8%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 two new production lines 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 .

Written by :	**Approved by :**
Name :……	Name :…….
Signature :……...	Signature :……
Date :……	Date :…….