

- Laboratories that serve the upgraded production area were previously licensed.
- After the tour, the required documents for area qualifications & equipment calibration & 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.
- Comments were presented to company representatives which were categorized as others.

Part 5: Areas inspected

Preparation area, filling area, packaging (primary and secondary)

Part 6: Description

- Upgrade the production line of solid area show compliance to GMP guidelines.
- Suitable layout showing adequate spaces for free logic process flow.
- Classification and Δp were revised and was found 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 regulatoryaccording 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 inspected upgraded production line, 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 and fulfillment of comments will be followed by The General Administration of Factories Inspection.