



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 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 area, water station, and microbiological and chemical 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.
- Wrap up meeting was held to inform the factory representatives with the committee final decision
- Some Comments were observed and stated on licensing inspection report that are classified as others

Part 5: Areas inspected

Preparation area, filling area, packaging areas, AHUs, warehouse, water treatment station, compressed air generators

Part 6: Description

- adding of production line of raw material (powder) 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

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 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 areas inspected, the people met, and the documents reviewed, and the follow up of the findings of the previous licensing inspection, as well as the corrective actions taken from the factory were considered to have been conducted at an acceptable level of compliance
- All the comments 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