Serial no.:0002/2026

Licensing Inspection Report Summary

Part 1: Manufacturer details:

1. **Manufacturer Name**: Egyptian Company for Production of Vaccines, Sera & Drugs (EGYVAC)
2. **Manufacturer Address**: 51 Wezaret El Zeraa Street. - Agouza - Giza.
3. **Owner Company** : Egyptian Company for Production of Vaccines, Sera & Drugs (EGYVAC) One of the Affiliated Companies of the Holding Company for Production of Biological Products and Vaccines (VACSERA) (S.A.E).,
4. **Technical License of Operation**: The factory was licensed on 13/1/2003 for manufacturing of vaccines, sera & biological products, which has granted the Technical License of Operation coded (LiHV2024010/0062005) with validity of 7 years ends on 3/6/2033.
5. **Licensed production lines:**

1- Building for Production of Concentrate Tetanus Toxoid (intermediate product).

2- Building of Diphtheria & Pertussis.

- Concentrates Area: Concentrate Diphtheria Toxoid, Concentrate Pertussis, Concentrate cholera & Concentrate Typhoid.
- Vaccines Mixing Area.

3- Building no.1 Production of vaccines & sera - filling & packaging of liquid biological product “insulin” in glass vials - oral drops in plastic containers.

4- Building no.2 Production of biological product “insulin” in glass vials - filling & packaging of liquid & lyophilized vaccines & sera in glass vials - production of Tuberculin product.

5- Building no. 60 Production of vaccines and sera (vial & ampoule combi-line) - filling of water for injection in glass ampoules.

Part 2: Background

The licensing inspection team is responsible for conducting a pre-inspection review of the factory to ensure that its facilities, buildings, and equipment are suitable for the intended license.
This license is specifically required for the production of vaccines , sera & biological products ,

The licensing inspection team's review aims to verify that the factory meets all the necessary technical and regulatory standards stated in Part 5 .

Once compliance is confirmed, The General Administration of Factories Licensing issues The Technical License of Operation which enables the factory to start production.

Following the issuance of the license, the factory's operations are subject to ongoing monitoring and follow-up through regular GMP inspections.

Part 3: Licensing Inspections

3-1 December 2002 licensing inspection

Date: 23/12/2002

Scope: Licensing of new factory with sterile area for production of concentrate tetanus toxoid (intermediate product).

Description:

The licensing inspection team assessed the sterile area for production of concentrate tetanus toxoid (intermediate product) in the manufacturing facility which covered the following:

- All areas matched the factory layout.
- The assessed area was found to be isolated from the rest of the entity buildings.
- Quality control (QC) laboratories : microbiological, chemical, and analytical testing facilities responsible for raw material testing, in-process control, and finished product release testing which contains the required equipment for analysis the raw materials and finished products .

- Warehouses : storage areas for raw materials, packaging materials, intermediates, finished products, and rejected or returned goods.
- Utilities: supporting systems including HVAC (Heating, Ventilation, and Air Conditioning), purified water systems, electric generator, waste disposal, Gowning areas, toilets .
- Documentation: including but not limited to qualification documentation, validation protocols and reports, equipment qualification documents, environmental monitoring data, standard operating procedures (SOPs) example for Bacterial Count – Particle Count – HVAC- Water System – Cleaning Procedure which were found to be complying.

Key Findings and corrective actions to be taken by the manufacturer:

The sterile area for concentrate tetanus toxoid production was found to be fully compliant across all assessed aspects

Compliance level And Conclusion:

Based on the areas inspected and the documents reviewed, The licensing inspection team decided that the sterile area complies with the required GMP standards and decided to grant the License to the factory.

3-2 June 2005 licensing inspection

Date : 22 /6/2005

Scope : licensing building (1) for production of sterile products for injection , eye drops and Polio Vaccine packed in plastic containers.

Description

The licensing inspection team assessed the manufacturing facility across all operational areas which covered the following:

- Production lines: for all manufacturing stages from raw material processing to final product formulation through production lines: sterile products : eye drops and Polio Vaccine.
- Preparation area : was found classified area class B .

- Filling areas: for aseptic filling where products are filled into their primary containers through 3 filling lines for vials , eye drops & polio vaccine in plastic tubes.
- Packaging areas: for secondary packaging (cartons, labels, leaflets)
- Warehouses: storage areas for raw materials, packaging materials, intermediates, finished products, and rejected or returned goods which was previously licensed .
- Cold rooms: temperature-controlled storage areas to ensure cold chain integrity for heat-sensitive products for vaccines which was previously licensed .
- Quality control (QC) laboratories: no laboratories in building 1, central labs. which was previously licensed will be used.
- Utilities: supporting systems including HVAC (Heating, Ventilation, and Air Conditioning), purified water systems, steam generation, compressed air were assessed.
- Documentation: including but not limited to qualification documentation , equipment qualification documents, environmental monitoring data were found complying.

Key Findings and corrective actions to be taken by the manufacturer:

Building (1) for production of sterile products for injection , eye drops and Polio Vaccine packed in plastic containers was found to be fully compliant across all assessed aspects

Compliance level And Conclusion:

Based on the areas inspected and the documents reviewed the licensing inspection team decided that the building (1) for production of sterile products for injection , eye drops and Polio Vaccine packed in plastic containers comply with the required GMP standards and grant the License add the new production lines .

3-3 November 2012 licensing inspection

Date : 7/11/2012

Scope : Licensing building of Diphtheria & Pertussis and Building of Vaccines Mixing.

Description : The licensing inspection team assessed the building of diphtheria & pertussis and building of vaccines mixing across all operational areas which covered the following:

- Preparation area: 1- For manufacturing of vaccines concentrates of diphtheria toxoid from preparation of seed culture & cultivation till storage 2-For manufacturing of pertussis from preparation of B2 media till storage .
- Mixing plant : for steps from preparation and sterilization of alum till release to be filled in the filling unit .
- Packaging areas: for secondary packaging (cartons, labels, leaflets) was previously licensed
- Warehouses & cold rooms: were previously licensed .
- Quality control (QC) laboratories: central laboratories which were previously licensed will be used in quality control testing .
- Utilities: supporting systems including HVAC (Heating, Ventilation, and Air Conditioning),
- The water system was previously licensed.
- Documentation : the required documents were reviewed , including but not limited to: qualification documentation, validation protocols and reports, equipment qualification documents, environmental monitoring data, standard operating procedures (SOPs) .

Key Findings and corrective actions to be taken by the manufacturer:

1- Premises of diphtheria & pertussis building and mixing building :
   - Interior finishing regarding coving require maintenance
   - No air curtains were found in the building entrance
   - Some Δ p gauges required to be installed

- Classification of washing area should be same class as that of production area
- Cascading of areas classification should be reviewed
- Autoclave area classification should be reviewed .
- Drains were found to be non sanitary

Corrective actions to be taken by manufacturer :

- Review and maintain all covings .
- Air curtains should be installed on the building entrance
- Install Pressure gauges for contentious monitoring of differential pressure .
- Area Classification has to be maintained in both washing area and autoclave area .
- Drains should be changed to sanitary.
- Maintain cascading of areas classification

2- HVAC :

- Area of AHUs was unclean and require maintenance.

Corrective actions to be taken by manufacturer :

- Clean and maintain the area of the AHUs and the HVAC

Compliance level And Conclusion:

The outcome of the licensing inspection indicates that the facility demonstrated a satisfactory level of GMP compliance across all assessed areas, with no findings that would materially compromise product quality, patient safety, or regulatory conformity.

Observations would typically be addressed through the facility , that would be fulfilled by the EDA inspectors , thus the licensing inspection team decided to grant the factory license .

3-4 November 2017 Licensing Inspection

Date: 14/11/2017

Scope : licensing for building (60) for production of vaccines and sera (vial & ampoule combi-line) and filling of water for injection in glass ampoules.

Description :

The licensing inspection team assessed the manufacturing building across all operational areas which covered the following:

- Production lines: for all manufacturing stages which is located in the first floor ,and starts from raw material processing to final product formulation of vaccines to be transferred to filling area after quality control testing approval .
- Filling areas : aseptic filling area Class B for filling of vaccines and sterile products in their primary containers (vials) located in the first floor.
- Packaging areas : for secondary packaging (cartons, labels, leaflets) which is present in the same building and is located in the first floor of the building . .
- Warehouse : storage areas for raw materials, packaging materials, rejected or returned goods in the ground floor of the building.
- Cold rooms : temperature-controlled storage areas ensuring cold chain integrity for heat-sensitive products for vaccines and sterile products which is located in the ground floor in the building .
- Quality control (QC) laboratories : microbiological, chemical, and analytical testing of raw materials , IPC & finished products is done in the main laboratory of the factory which was previously licensed .
- Utilities :supporting systems including HVAC (Heating, Ventilation, and Air Conditioning), water systems, steam generation, compressed air .
- Documentation : The licensing inspection team reviewed the required documents, including but not limited to: qualification documentation, equipment qualification documents, environmental monitoring data, standard operating procedures (SOPs).

Findings and corrective actions to be taken by the manufacturer:

1. Production area & warehouse
    - Regarding SOPs : the following procedures should be present as : in gowning rooms separation between the pre- and post-gowning stages , procedures governing the entry and exit of raw materials and finished products
    - There are no means of monitoring temperature in reception area .
    - Differential pressures should be adjusted.
    - Air flow between tunnel and the Class B filling area should be controlled by firm sealing between the two rooms.
    - Air return to the ventilation unit for garment storage lockers should be checked.
    - The oven door in the sterile tool unloading room should comply to sanitary requirements ..
    - Table for wrapping instruments prior to their entry into the autoclave is not present.

- Installation of the LAF filters of the filling machine aren't completed.
- Shelves of warehouse aren't installed.

Corrective Actions to be taken by Manufacturer:

- Preparation of all the SOPs concerning the operation specially for visual gowning procedures and flow of raw materials , intermediates and finished products .
- Install temperature monitors in the reception area
- Adjust differential pressures to the required values which are stated on the area layout to comply to GMP guidelines and should be continuously monitored.
- Firmly close the space between the tunnel and the Class B filling area to prevent any the leak of air around the tunnel to filling area
- Check the ventilation system for garment storage lockers to allow air return to the ventilation unit.
- The oven door in the sterile tool unloading room should be maintained.
- Table for wrapping instruments prior to their entry into the autoclave should be installed.
- LAF filters of the filling machine should be completed Prior production.
- Shelves of warehouse should be installed.

2. Utilities :
    - Filters of compressed air connections aren't completely installed.
    - Washing of sterile gowns should be clarified
    - Supply, return ducts of the HVAC aren't identified.
    - Cladding of all duct system and chilled water system aren't done .

    Corrective Actions to be taken by Manufacturer:

    - Install Filters of compressed air connections prior production.
    - Clarify the mean of sterile garments washing and sterilization in clear SOPs
    - Identify all supply , return ducts .
    - Cladding of all duct system and chilled water system .
3. Cold room:
    - Installation of the finished product storage shelving inside the cold room must be completed.

    Corrective Actions to be taken by Manufacturer:

    - Complete installation of storage shelving inside the cold room

Compliance level And Conclusion

Based on the areas inspected and the documents reviewed, all the non -compliances observed during the licensing inspection were listed in the full report and were addressed to the manufacturer .

The decision was that the factory should submit corrective action to the findings observed to comply with the required GMP standards stated in Part 5 and the findings should be followed up from the inspection team and the license was granted to the factory .

3-5 December 2023 Licensing Inspection

Date: 27/12/2023 & 1/1/2024

Scope : Issuance the Technical License for Operation

Description : The licensing inspection team assessed the manufacturing building across all operational areas , packaging , warehouses which covered the following:

1- Building for Production of Concentrate Tetanus Toxoid (intermediate product).
2- Building of Diphtheria & Pertussis:
   - Concentrates Area: Concentrate Diphtheria Toxoid, Concentrate Pertussis, Concentrate cholera & Concentrate Typhoid.
   - Vaccines Mixing Area.
3- Building no.1 Production of vaccines & sera - filling & packaging of liquid biological product “insulin” in glass vials - oral drops in plastic containers.
4- Building no.2 Production of biological product “insulin” in glass vials - filling & packaging of liquid & lyophilized vaccines & sera in glass vials - production of Tuberculin product.
5- Building no. 60 Production of vaccines and sera (vial & ampoule combi-line) - filling of water for injection in glass ampoules.
6- Building of central filling.
7- Building of central packaging .

Conclusion

Issuing the Technical License for Operation instead of old Ministry of health license .

3-6 October 2025, licensing inspection

Date: 15/10/2025

Scope : Licensing new cold rooms

Description:

The licensing inspection team assessed the cold rooms across all the factory to ensure the compliance of the cold rooms to the standards stated in part 5

The cold rooms were assessed according to the identification list submitted by the factory as follows :

A- Cold area (1) in building no. (7) contains (6) cold rooms & (5) deep freezers.

B- Cold area in building no. (30) contains (10) cold rooms.

C- Cold area (3) in building no. (6) contains (6) cold rooms.

D- Cold area (4) in building no. (3) contains (4) cold rooms.

E- Cold area (5) in building no. (5) “HR building” in the ground floor contains (2) cold rooms.

F- Cold area (6) in building no. (5) contains (3) cold rooms.

G- Cold area (7) in building no. (7) contains (2) cold rooms.

H- Veterinary company cold area in building no. (10) “Veterinary company building” in which the first floor contains (4) cold rooms & the second floor contains (1) cold room.

I- Research cold room in building no. (9) “Research building” in the first floor.

J- Media cold room in building no. (5) “HR building” in the second floor**.**

Findings and corrective actions to be taken by the manufacturer:

1-A sign should be placed indicating the cold rooms assigned for expired items.

2-Cold rooms Codes should match that on the layout

3- A drainage network should be constructed to the cold room that is located in a floor level lower than the road level

Corrective actions by manufacturer:

1-Place a sign on rooms assigned for expired items.

2-Submitting a matched layout to reality

3-Construct a drainage network for cold rooms located in lower level

Compliance level And Conclusion

The committee decision was that the inspected cold rooms comply with the required standards and the committee members decided to grant the Technical License of Operation to the factory.

Part 4: Abbreviations

EDA : Egyptian Drug Authority
GMP : Good Manufacturing Practice
HVAC : Heating, Ventilation, and Air Conditioning
I.Q : Installation Qualification
LAF : Laminar Air Flow
O.Q : Operational Qualification
Q.C: Quality Control
SOPs : Standard Operating Procedures
WHO : World Health Organization

Part 5: 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/