Central Administration of Pharmaceutical Institutions Licensing
General Administration of Factories Licensing

The Regulatory Guideline for work Procedures of the General Administration of factories licensing

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1. Introduction:

The General Administration of factories licensing is responsible for establishing a system and instructions for:

- Reviewing the layouts of factories within the scope of the Egyptian Drug Authority (EDA) that are intended to be licensed, as well as reviewing any modifications or additions to production lines, the addition of non-production areas, or the layouts of plasma collection centers.
- Ensuring compliance with Good Manufacturing Practice (GMP) requirements for the factories licensing within the scope of the Egyptian Drug Authority, prior to the issuance of Technical license of operation
- Ensuring compliance with Good Manufacturing Practice (GMP) requirements within the procedures for adding a new production line to a licensed factory, adding or replacing a machine, canceling a production line, or approving any modification to the factory that does not involve changes to the motive power such as modifying the layouts or modifications to quality control laboratories.
- Ensuring compliance with Good Storage Practice (GSP) requirements for the addition, modification, or cancellation of a storage facility within the factory premises, or for the addition of an accessory store affiliated with a licensed factory.
- Issuing Technical license of operation for factories within the scope of the Egyptian Drug Authority.
- Adding or modifying any data included in the factory's Technical license of operation that does not require a licensing inspection, including but not limited to: changing the name of an authorized person, adding or canceling a plot of land for the factory, changing the name of the factory/owner, transferring of factory ownership, registering or changing of factory managers, proving / renewing laboratory or sterilization contracts.
  issuance of certified copies of the factory's Technical license of operation issued by the General Administration of factories Licensing for documentation abroad

2. Definitions

Factories within the Authority's Scope of Work:

Factories subject to the supervision of the Egyptian Drug Authority and governed by the provisions of both Law No. 127 of 1955 concerning the Practice of the Pharmacy Profession, and Law No. 151 of 2019 concerning the Establishment of the Egyptian Drug Authority. These include factories manufacturing human, veterinary, biological, and herbal medicines; vaccines and sera; radioactive isotopes; cosmetics; disinfectants; Medical devices (sterile, non-sterile, and those prepared for sterilization); laboratory and diagnostic reagents; prosthetics; Orthotics; and mobility aids.

- **Pharmaceutical Products:**

Any product or preparation containing any ingredient or combination of ingredients used for the purpose of treatment, prevention, or diagnosis in humans or animals, or described as having any other medical effect, or intended to restore, correct, or modify physiological functions through a pharmacological, immunological, or metabolic effect on public health, in accordance with the applicable references and standards, as well as any preparations or ingredients that may be developed in accordance with scientific advancements and/or international standards and references.

- **Pharmaceutical Factory:**

The Authorized Representative is the person delegated by the license-holding company to legally represent it in all matters related to the factory's. Technical license of operation

• Accessory store Affiliated with the Factory

An off-site warehouse affiliated with the factory is a storage facility located outside the factory premises, used for storing quantities exceeding the needs of the pharmaceutical establishment
A pharmaceutical institution licensed to manufacture pharmaceutical products or raw materials.

- **Good Manufacturing Practices (GMP):**

Steps to be followed to ensure that the final product aligned with the required specifications.

- **Good Storage Practices (GSP):**

The application of a set of standards and rules to ensure the safe and efficient storage of pharmaceutical products and medical devices in a manner that preserves their quality.

- **Biological Products:**

Products containing one or more active ingredients produced or derived from a biological source, including but not limited to human vaccines, serum, blood and plasma products and derivatives, also products manufactured using biotechnology and the like,as well as, any products or substances that may be developed in accordance with scientific advancements or international standards and references.

- **Raw Materials:**

Active or inactive ingredients used in the manufacture of pharmaceutical products and medical devices , excluding materials used for packaging.

- **Cosmetics**:

Products containing one or more ingredients prepared for use on the external parts of the human body (such as the skin, hair, nails, lips, face, and the external genitalia).
or the teeth and the mucous membranes lining the oral cavity, for the purposes of cleaning, perfuming, protecting, keeping them in good condition, or changing or improving their appearance, or changing or improving breath odor.
The guidelines issued by COLIPA and the European Cosmetic Regulation (EEC) No. 1223/2009 and its amendments concerning cosmetic products shall be the reference for the evaluation of such products.

- **Medical devices :**

Any device, ingredient, instrument, machine, apparatus,or application tool ,including what is implanted, planted , laboratory reagents, electronic programs, or other similar or related materials and objects, manufactured by the manufacturer for human use, individually or in combination, for one or more of the following specific medical purposes:
-Diagnosis, prevention, monitoring, treatment, or alleviation of disease.
-Diagnosis, monitoring, treatment, alleviation, or compensation for an injury or disability.
Verification, replacement, modification, or support of anatomical or functional processes.
-Supporting or sustaining life
-Controlling pregnancy.
-Disinfection of medical supplies.
-Providing information through laboratory testing of samples derived from or taken from the human body.
Provided that the primary intended purpose is not achieved through pharmacological, immunological, or metabolic effects in or on the human body, however, such means may assist the medical device in achieving its intended function.

The supply shall not act or exhibit its effect through pharmacological (drug-related), immunological, or metabolic means. A product may be considered a medical device if these methods secondarily assist in fulfilling its function.

- **Radioactive Isotopes:**

These are inorganic and organic compounds, peptides, proteins, monoclonal antibodies and their fragments, and oligonucleotides identified as radionuclides, provided that their shelf lives range from a few seconds to several days.

- **Disinfectants:**

Preparations that kill or inhibit the growth of disease-causing microorganisms, whether bacteria, viruses, fungi, or yeasts, to reduce or prevent disease, without having any other therapeutic purpose and without exerting any pharmacological effect.

- **Production Line:**

A series of sequential operations carried out in a factory, in which raw materials are used through successive processes to produce a final product suitable for consumption, or whereby components are assembled to form a final product.

- **factory layout**

A diagram showing production areas, storage facilities, laboratories, the water treatment plant, the air handling unit, and all factory services. It also shows the flow of personnel (workers), the flow of raw materials, pressure differentials between the various production areas, and the air classification of different areas.

- **Production Machinery:**

Machines used during the manufacturing stages of pharmaceutical products and medical Devices

- **Related Authorities:**

-General Authority for Industrial Development, Investment Authority,General Authority for Suez Canal Economic Zone

- **Authorized Representative for the** Technical license of operation

This is the person authorized by the licensing company to legally represent it in obtaining the factory's.Technical license of operation

- **an accessory store Affiliated with the Factory:**

A storage facility located outside the factory premises where surplus stock is stored.

- **Plasma Derivatives:**

Biological products derived from components of human blood plasma , such as albumin, clotting factors, and other plasma-derived products.

3-Procedures

3-1 Reviewing the layouts of factories within the scope of the Egyptian Drug Authority (EDA) that are intended to be licensed, as well as reviewing any modifications or additions to production lines, the addition of non-production areas, or the layouts of plasma collection centers.

"This procedure shall be carried out through the General Administration of factories licensing

1 .The factory shall submit a request for the review of the layout using the designated form, signed by the Chairman of the Board of Directors or the duly authorized signatory. The request shall be submitted via the General Administration of factories Licensing's online portal, attached to a copy of the layout (PDF) to be presented to the layout Review Committee.

2 .The General Administration of factories Licensing shall review the request and determine the fee for the layout review service in accordance with the decision of the Chairman of the Egyptian Drug Authority No. 273 of 2021, and shall send an email to the factory indicating the applicable service fee.

3 .The factory shall pay the service fee and submit the original payment receipt to the General Administration of factories Licensing's online portal.

4. The General Administration of factories Licensing shall schedule a meeting for the layout Review Committee and notify the factory of the scheduled date via email

5-The layout shall be reviewed in the presence of the factory's representatives, provided that they are representatives of production and of the engineering management, to present the layout to the Committee.

❖ Hard copies shall be submitted to the layout Review Committee as follows:

-The original, duly approved request for layout review.

-Two hard copies of the layout, each placed in an envelope file.

--layout Specifications (Consisting of Two sheets):

-Sheets (1): Illustrates the pathways of raw materials, intermediate product , waste disposal, and personnel flow.

-Sheets (2): Illustrates the air classification and room pressure values for air-classified areas.

Notes:

- The sheet key must list all sheet details.

(The company name, color coding, key for any abbreviations, and Activity of the production line)

-The font used for all layout details must be clear.

-When adding a new production line, the line's location on the layout must be clearly indicated, (i.e., shading the remaining licensed area).

-When upgrading a production area, the licensed production area must be shaded on the layout.

-Please ensure there are no spelling errors.

LAFs, hatches, autoclaves, and lyophilizers must be clarified (if any)

- Noting that the layout Review Committee is committed to reviewing only the production lines stated in the review request, their number, and the service fees paid for them.

6- If there are any comments, the factory shall submit a request for re-review after fulfilling the committee's comments.

The request for fulfillment of comments shall be submitted using the designated form via the electronic portal of the General Administration of factories Licensing, in order to re-present the layout to the competent committee, with a maximum of three fulfillment review sessions.

6-If the layout is approved by the Review Committee, an approval letter for the layout shall be issued, accompanied by a hard copy of the approved layout.

3-2 Ensuring compliance with Good Manufacturing Practice (GMP) requirements for the factories licensing within the scope of the Egyptian Drug Authority, prior to the issuance of Technical license of operation

"This procedure shall be carried out in coordination with the relevant authority"

- <u>For factories affiliated with the General Authority for Industrial Development:</u>

1. The factory shall submit a request for a joint committee to the General Authority for Industrial Development, specifying the activity of the factory to be licensed and the production lines, and attaching the following documents:

Personal documents of the authorized representative (license holder): -A copy of the National ID card (original to be presented for review). -An original criminal record certificate indicating no prior convictions for the license holder, valid and addressed to the Egyptian Drug Authority. - An original birth certificate or an official extract thereof for the license holder.
layout of the site to be licensed, submitted in one original and two copies, stamped by a consulting engineer or the factory's engineering department, clearly showing the following: Personal flow,Material flow,Room classes,Differential pressure.
Articles of Association/ Investment Gazette
A copy of the land allocation decision (original for review).
A copy of the commercial register (original for review).
A copy of the tax card (original for review).
A receipt proving payment of the inspection fee of 5 Egyptian pounds (postal order addressed to the Egyptian Drug Authority).
The original approval of the General Authority for Investment / Suez Canal Economic Zone for conducting inspection by the Egyptian Drug Authority.(for factories affiliated with free zones / Suez Canal Economic Zone)
A copy of the valid operating license issued to the factory by the General Authority for Investment/Suez Canal Economic Zone for factories affiliated with free zones/Suez Canal Economic Zone)

2 .The General Authority for Industrial Development shall send a copy of the application submitted by the factory to the General Administration of factories licensing at the Egyptian Drug Authority.
3. A joint committee shall be conducted by the Egyptian Drug Authority and the General Authority for Industrial Development to ensure compliance with Good Manufacturing Practices (GMP) requirements, in preparation for issuing the technical license of operation for the factory by the Egyptian Drug Authority

❖ Notes:-

In the case of factories affiliated with any of the following entities:(1. The General Authority for Investment and Free Zones (whether a Free Zone or an Investment Zone), or 2.The Suez Canal Economic Zone) the application for the license and the required documents mentioned previously are submitted directly to the General Administration of factories Licensing at the Egyptian Drug Authority.

3-3 .1 Ensuring compliance with Good Manufacturing Practice (GMP) requirements within the procedures for adding a new production line to a licensed factory, adding or replacing a machine, canceling a production line

"This procedure shall be carried out in conjunction with the relevant authority"

❖ With regard to factories affiliated with the General Authority for Industrial Development :

1 .The factory shall submit an application to the General Authority for Industrial Development, specifying the type of the required modification and attaching the
layout
2 .The General Authority for Industrial Development shall send a copy of the application submitted by the factory to the General Administration of factories Licensing.
3. A joint committee shall be conducted by the Egyptian Drug Authority and the General Authority for Industrial Development to verify compliance with Good Manufacturing Practices requirements, in preparation for issuing the amended the technical license of operation by the Egyptian Drug Authority.(If necessary)

In the case of factories affiliated with any of the following entities:(1. The General Authority for Investment and Free Zones (whether a Free Zone or an Investment Zone), or 2.The Suez Canal Economic Zone) the required documents shall be submitted directly to the General Administration of factories Licensing at the Egyptian Drug Authority

3-3.2approving any modification to the factory that does not involve changes to the motive power such as modifying the layouts or modifications to quality control laboratories.

"This procedure shall be carried out through the General Administration of factories Licensing"

1- The factory shall submit the following documents via the online portal of the General Administration of factories Licensing:

-Application on the designated form signed by the chairman of the board of directors or the one who has the right to sign.

- An application submitted on the designated form, signed by the Chairman of the Board or the authorized signatory, clearly stating the required modification.

- The layout before and after the modification.

- An authorization letter appointing the company's representative to deal with the Egyptian Drug Authority / Central Administration for Pharmaceutical institutions Licensing,(the General Administration of factories licensing), and to receive and deliver all company-related documents, provided that the authorization should be certified by the bank, verifying the signature of the authorized signatory, in accordance with the Administration's powers.

2. A licensing inspection shall be conducted by the Egyptian Drug Authority, and the technical operating license of the factory shall be updated, (if deemed necessary.)

3-4.1 Ensuring compliance with Good Storage Practice (GSP) requirements for the addition, modification, or cancellation of a storage facility within the factory premises

"This procedure shall be carried out in coordination with the relevant authority"

❖ With regard to factories affiliated with the General Authority for Industrial Development:

1. The factory shall submit an application to the General Authority for Industrial Development, attaching the layout of the storage facility.

2 .The General Authority for Industrial Development shall send a copy of the application submitted by the factory to the General Administration of factories licensing at the Egyptian Drug Authority.

3. A joint committee shall be conducted by the Egyptian Drug Authority and the General Authority for Industrial Development to verify compliance with Good Manufacturing Practices requirements, in preparation for issuing the amended technical license of operation by the Egyptian Drug Authority.(If necessary)

❖ Notes:-

In the case of factories affiliated with any of the following entities:(1. The General Authority for Investment and Free Zones (whether a Free Zone or an Investment Zone), or 2.The Suez Canal Economic Zone) the application for the license shall be submitted directly to the General Administration of factories licensing with the required documents

3-4.2Ensuring compliance with Good Storage Practice (GSP) requirements for the addition of an accessory store affiliated with a licensed factory

"This procedure shall be carried out through the General Administration of factories Licensing"

1-The factory shall submit an application for a accessory store license affiliated with a licensed factory, using the designated form, signed by the Chairman of the Board or the authorized signatory, and accompanied by the required documents, through the electronic portal of the General Administration of factories Licensing, as follows:

-Three copies of the approved layout of the site.

-A document proving premises ownership. (A copy of a valid and notarized lease or ownership contract (issued by the Real Estate Registry or a court judgment, provided that the storage facility is licensed as a commercial activity and not residential or administrative. (the original document shall be presented for review)
-A receipt evidencing payment of the inspection fee of 3 Egyptian pounds.
-An original document issued by the Electricity Company confirming the existence of an independent electricity meter inside the premises, clearly stating the meter number and the address of the premises,or an original document issued by the Electricity Company confirming a permanent electricity connection until the meter is installed.
-A declaration from the institution owner stating that sales will not be conducted through the accessory store and that no pharmaceutical products belonging to any other institution will be stored there.
-A valid authorization for the company's representative to deal with the Egyptian Drug Authority and to receive and deliver all company documents, provided that the authorization should be authenticated by bank signature for the authorized signatory.
2-The General Administration of factories licensing shall conduct the necessary licensing inspections to ensure compliance with Good Storage Practices (GSP).
- The General Administration of factories Licensing shall issue the accessory store license and update the technical license of operation
-The factory shall pay a service fee of EGP 20,000 (Twenty Thousand Egyptian Pounds) upon receipt of the accessory store license.

3-4 Issuing Technical license of operation for factories within the scope of the Egyptian Drug Authority.

This procedure shall be carried out through the General Administration of factories Licensing.
1. The factory shall submit an application for the issuance of the technical license of operation , using the designated form, signed by the Chairman of the Board or the authorized signatory, along with the required documents, through the electronic portal of the General Administration of factories Licensing, as follows:
-Documents pertaining to managers, in accordance with the Regulatory Guide for the Registration of Managers of Pharmaceutical and Medical devices Factories.
-A copy of the Operating License issued by the General Authority for Industrial Development (if applicable).
- An authorization letter appointing the company's representative to deal with the Egyptian Drug Authority / Central Administration for Pharmaceutical institutions Licensing,(the General Administration of factories licensing), and to receive and deliver all company documents, provided that the authorization should be certified by the bank with the validity of the signature of the authorized signatory
2. The General Administration of factories shall review the submitted documents within ten (10) working days and notify the applicant of any additional required documents.

3-If all documents are duly completed, the technical license of operation shall be issued within ten (10) working days. If the factory fails to submit all required documents within 15 working days, the application shall be archived.

4- The factory shall pay the prescribed fee of EGP 5,000 (Five Thousand Egyptian Pounds) per production line upon receipt of the technical license of operation.

3-6Adding or modifying any data included in the factory's Technical license of operation that does not require a licensing inspection, including but not limited to: changing the name of an authorized person, adding or canceling a plot of land for the factory, changing the name of the factory/owner, transferring of factory ownership, registering or changing of factory managers, proving / renewing laboratory or sterilization contracts.

This procedure shall be carried out through the General Administration of factories licensing.

1. The factory shall submit an application to modify the technical license of operation., using the designated form, signed by the Chairman of the Board or the authorized signatory, and accompanied by all required documents in accordance with the type of addition or modification requested, as specified in the table below.

The application shall be submitted through the electronic portal of the General Administration of factories Licensing, as follows:

1.6.1 Procedure for changing the name of the authorized representative the factory's the technical license of operation.

A. Personal documents of the new authorized person (license holder), as follows:

- Copy of national ID card (original for review)

- Original official extract of birth certificate

- Original valid criminal record certificate addressed to the General Administration of factories Licensing - Egyptian Drug Authority

- Copy of Commercial Register (original for review)

- A valid authorization letter appointing the company's representative to deal with the Egyptian Drug Authority / Central Administration for Pharmaceutical institutions Licensing,(the General Administration of factories Licensing), and to receive and deliver all company documents, provided that the authorization should be authenticated by bank signature for the authorized signatory, in accordance with the Administration's powers

❖ **Note:**

The authorized person (license holder) shall be the Chairman of the Board of Directors of the company owning the factory, having the right of signature in accordance with the powers stated in the Commercial Register, or a person duly authorized on his behalf under a formal authorization certified as to the authenticity of the signature by a bank.

3.6.2 Factory Address Update Procedure (Addition or Cancellation a Plot of Land):

A copy of the updated Commercial Register (Original for review)

A copy of the updated Tax Card (Original for review).

A copy of Premises Ownership/Land Allocation document (Original for review).

An Investment Gazette showing the amended name(if applicable).

A copy of the Operating License issued by the General Authority for Industrial Development(if applicable)

- A valid authorization letter appointing the company's representative to deal with the Egyptian Drug Authority / Central Administration for Pharmaceutical institutions Licensing,(the General Administration of factories Licensing), and to receive and deliver all company-related documents, provided that the authorization should be authenticated by bank signature for the authorized signatory, in accordance with the Administration's powers.

3.6.3 Change of the Factory Name / Owner Name Procedure:

A copy of the updated Commercial Register (Original for review)

A copy of the updated Tax Card (Original for review).

An Investment Gazette showing the amended name(if applicable).

A copy of the Operating License issued by the General Authority for Industrial Development(if applicable)

- A valid authorization letter appointing the company's representative to deal with the Egyptian Drug Authority / Central Administration for Pharmaceutical institutions Licensing,(the General Administration of factories Licensing), and to receive and deliver all company-related documents, provided that the authorization should be authenticated by bank signature for the authorized signatory, in accordance with the Administration's powers.

3.6.4 Procedure for Transferring Ownership of a Factory:

A notarized sale contract between the new owner and the seller.

A copy of the updated Commercial Register after the sale of the factory.

A copy of the amended Tax Card.

A copy of the Operating License issued by the General Authority for Industrial Development(if applicable)

- A valid authorization letter appointing the company's representative to deal with the Egyptian Drug Authority / Central Administration for Pharmaceutical institutions Licensing,(the General Administration of factories Licensing), provided that the authorization should be authenticated by bank signature .

3.6.5 Procedure for Registering/Changing the Names of Managers on the technical license of operation.

All required documents shall be submitted according to the type of factory, as specified in the Regulatory Guide for the Registration of Managers of Pharmaceutical and Medical devices Factories.

3.6.6 Procedure for Documentation / Renwal of Laboratory or Sterilization Contracts

First:Laboratory Contract:(For factories producing pharmaceutical products and medical devices)

A copy of the laboratory contract concluded with a factory subject to the Egyptian Drug Authority's supervision, specifying the types of tests contracted for, provided that the contract shall be for a fixed term and certified as to the authenticity of the signature by a bank or by the Real Estate Publicity Department on the signature of the contracted factory.

- A valid authorization letter appointing the company's representative to deal with the Egyptian Drug Authority / Central Administration for Pharmaceutical institutions Licensing,(the General Administration of factories Licensing), provided that the authorization should be authenticated by bank signature.

Second: Sterilization Contract (For medical devices factories)

A copy of the sterilization contract, provided that it is for a fixed term and subject to the Egyptian Drug Authority's supervision. If the factory contracts with another facility not subject to the EDA inspection, the factory shall submit a declaration of its willingness to allow pharmaceutical inspection to enter the sterilization facility at any time.The sterilization contract shall be certified as to the authenticity of the signature by a bank or or by the Real Estate Publicity Department on the signature of the contracted factory.

- A valid authorization letter appointing the company's representative to deal with the Egyptian Drug Authority / Central Administration for Pharmaceutical institutions Licensing,(the General Administration of factories licensing), provided that the authorization should be authenticated by bank signature.

2. The General Administration of factories licensing shall review the submitted documents within ten (10) working days and notify the applicant of any additional required documents.
3-If all documents are duly completed, the technical license of operation.shall be issued within ten (10) working days. If the factory fails to submit all required documents within 15 working days, the application shall be archived.

3-4 issuance of certified copies of the factory's Technical license of operation issued by the General Administration of factories Licensing for documentation abroad.

"This procedure shall be carried out through the General Administration of factories licensing"

1. The factory shall submit an application for the issuance of the the technical license of operation, using the designated form, signed by the Chairman of the Board or the authorized signatory, along with the required documents, through the electronic portal of the General Administration of factories Licensing, as follows:

-A copy of the most recent the technical license of operation issued by the General Administration of factories Licensing.

-A receipt for payment of the service fee (1000 EGP).

-A copy of an authorization addressed to the Egyptian Drug Authority / Central Administration for Pharmaceutical institutions Licensing (General Administration of factories Licensing) appointing the factory's representative authorized to deal with the Egyptian Drug Authority, provided that the original authorization shall be presented for review upon receipt of the certified true copy.

2. The General Administration of factories Licensing shall review the submitted documents within ten (10) working days and notify the applicant of any additional required documents.
3-If all documents are duly completed, the technical license of operation shall be issued within ten (10) working days. If the factory fails to submit all required documents within 15 working days, the application shall be archived.

4-References

4.1 Law No. 127 of 1955 concerning the Practice of the Pharmacy Profession.

4.2 Law No. 151 of 2019 regarding the Establishment of the Egyptian Drug Authority and its Executive Regulations.

4.3 Law No. 15 of 2017 concerning the Facilitation of Procedures for Granting Licenses to Industrial Establishments and its Executive Regulations.

4.5 Minister of Health Decree No. 435 of 2006 concerning the Egyptian Code of Good Manufacturing Practices for Biological Products, Sera, and Vaccines.

4.6 Decision of the Chairman of the Egyptian Drug Authority No. 99 of 2021 concerning Disposal of Pharmaceutical and Medical Supplies Factories.

4.7 Decision of the Chairman of the Egyptian Drug Authority No. 271 of 2021 concerning the Requirements for licensing storage facilities affiliated with pharmaceutical institutions.

History Table

Version No.	Issue date	Summary of Changes
2	**2/0**	New issue due to change of central administration of operation to Central Administration of Pharmaceutical Institutions Licensing