Central Administration of Pharmaceutical Institutions Licensing
General Administration of Factories Licensing

Regulatory Guideline for the Procedures of Operations Licensing of Cosmetics Factories

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1. Introduction:

The General Administration for Factories Licensing is the competent authority responsible for establishing the system and instructions for the following purposes:

- Reviewing the layouts of Cosmetics Factories to be licensed, as well as reviewing any modifications or additions to production lines, or the addition of non-production areas within such facilities.
- Verifying compliance with Good Manufacturing Practices (GMP) requirements for the licensing of Cosmetics Factories , as a prerequisite for the issuance of the technical license of operation
- Verifying compliance with Good Manufacturing Practices (GMP) requirements as part of the procedures for adding a new production line to a licensed facility, adding or replacing equipment, cancelling a production line, or approving any modification within the facility that does not involve changes to the driving power systems, such as amendments to the factory layout or modifications in the quality control laboratories.
- Verifying compliance with Good Storage Practices (GSP) requirements for the addition, modification, or cancellation of a warehouse within the factory premises, or for the addition of an accessory store (an off-site warehouse) affiliated with a licensed factory.
- Issuing technical licenses of operation for Cosmetics Factories .
- Performing the addition or modification of any data in the facility's technical operating license that does not require an on-site licensing inspection (for example, but not limited to: changing the name of the authorized representative- adding/cancelling a land plot of the factory- changing the factory name/owner- transferring factory ownership- registering/changing the factory manager- verifying/renewing laboratory contracts)).
- • Extracting certified copies of the technical operating license of a cosmetic manufacturing facility for documentation purposes abroad

2. Definitions

• Cosmetic Products:
Products that contain one or more substances intended for use on the external parts of the human body (skin, hair, nails, lips, face, and the external genital organs) or on teeth and the mucous membranes of the oral cavity for the purposes of cleaning, perfuming, protecting, maintaining in good condition, or altering/improving appearance or oral odor. The guidelines of COLIPA and the European Cosmetic Regulation (EEC 1223/2009), including its amendments, are considered the reference standards for evaluating cosmetic products.

• Good Manufacturing Practices (GMP)
Steps to be followed to ensure that the final product complies with the required specifications.

•Good Storage Practices (GSP)
Following a set of standards and rules to ensure that cosmetic products are stored safely, efficiently, and in a manner that preserves their quality.

•Production Line:
A set of sequential operations carried out in a factory where raw materials are used through successive processes to produce the final product, making it suitable for consumption, or where components are assembled to form the final product

Factory layout :
A schematic layout illustrating the production areas, warehouses, Laboratories, water treatment station, air handling unit (AHU), and all factory utilities. The layout also demonstrates the flow of personnel (workers), the flow of raw materials, pressure differentials between the various production areas, and the different air classifications of the factory zones.

• Production Machines:
Production machines are equipment used during the various stages of manufacturing cosmetic products and medical supplies.

• Relevant Authorities:
General Authority for Industrial Development (IDA) - General Authority for Investment (GAFI)- Suez Canal Economic Zone Authority (SC Zone)

• Authorized Representative for the technical license of operation :
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

3-Procedures

3-1 Reviewing the layouts of Cosmetics Factories to be licensed, as well as reviewing any modifications or additions to production lines, or the addition of non-production areas within such facilities.

"This procedure shall be carried out through the General Administration for Factories Licensing"

1-The factory shall submit an application for the review of the layout using the designated form, duly signed by the Chairman of the Board of Directors or the authorized signatory. The application shall be submitted through the electronic portal of the General Administration for Factories Licensing, and shall be accompanied by a copy of the layout (PDF) to be presented to the layout Review Committee.

2-The General Administration for Factories Licensing shall examine /review the application and determine the service fee for reviewing the layout , 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 specifying the applicable fee.

3-The factory shall pay the prescribed service fee and submit the original payment receipt to the service counter of the General Administration for Factories Licensing.

4- The General Administration for 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, who shall include a representative from the Production Department and a representative from the Engineering Department, for the purpose of presenting the layout to the Committee.

***The following hard copies shall be submitted for presentation to the layout Review Committee:**

-The original, duly approved application for layout review.

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

layout **Specifications (Consisting of Two Sheets):**

- **Sheet (1):** Illustrates the flow paths, including: raw materials □-intermediate products□ waste disposal- personnel movement.
- **Sheet (2):** Illustrates the air classification and the room differential pressure values *(for air-classified areas).*

Notes:

-The drawing legend (KEY) shall clearly state all details shown on the drawings, including the company name, color coding, keys for any abbreviations, and the activity of the production line.

-All lines and details in the layout **must be clear and legible**.

- When **adding a new production line**, its location must be clearly indicated on the layout, and the **remaining licensed areas shall be shaded** accordingly.

-When **upgrading a production area**, the **licensed production area shall be shaded** on the layout

-Care must be taken to avoid spelling and typographical errors.
LAFs, hatches, autoclaves, and lyophilizers must be clarified (if any).

*It should be noted that the layout-**Review Committee** is bound to review the production lines included in the submitted review request, along with their quantity, provided that the applicable service fees have been duly paid.

6- In the event that comments are issued, 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 through the electronic portal of the General Administration for Factories Licensing, in order to resubmit the drawings to the competent committee, with a maximum of three comments -fulfillment review committees.

7-If the layout are approved by the review committee, an official approval letter for the layout shall be issued, accompanied by a hard copy of the approved. Layout

3-2Verifying compliance with Good Manufacturing Practices (GMP) requirements for the licensing of Cosmetics Factories , as a prerequisite for the issuance of the technical license of operation

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

***With respect to factories affiliated with the General Authority for Industrial Development:**

1. The factory shall submit a request for a joint committee to the General Authority for Industrial Development, indicating the production lines, and enclosing the following documents:

Personal documents of the authorized person (license holder): -A copy of the valid National ID card (original to be presented for review). -The original criminal record certificate indicating no prior convictions for the license holder, valid and addressed to the Egyptian Drug Authority (EDA). -The original birth certificate or an official extract thereof for the license holder.
An original layout of the site to be licensed, along with two copies, duly stamped by a consulting engineer or the factory's engineering department, indicating the following: personal flow, material flow, room classes, and differential pressure.
Investment gazette / The company's articles of incorporation..
A copy of the land allocation decision (original to be presented for review).
A copy of the commercial register (original to be presented for review).
A copy of the tax card (original to be presented for review).
Proof of payment of the application review fee in the amount of EGP 5 (postal money order payable to the Egyptian Drug Authority).
The original approval issued by the General Authority for Investment or the Suez Canal Economic Zone for conducting the inspection by the Egyptian Drug Authority (for factories affiliated with free zones or the Suez Canal Economic Zone).
A copy of the valid license to practice the activity issued to the factory by the General Authority for Investment or the Suez Canal Economic Zone (for factories affiliated with free zones or the 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 for 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 Practice (GMP) requirements, in preparation for the issuance of the factory's technical license of operation by the Egyptian Drug Authority.

***Note:**

In the case of factories affiliated with any of the following entities: (1) -the General Authority for Investment and Free Zones, whether operating in a free zone or an investment zone; or (2) -the Suez Canal Economic Zone, the application for licensing, along with the previously mentioned required documents, shall be submitted directly to the General Administration for Factories Licensing at the Egyptian Drug Authority.

3-3.1 Verifying compliance with Good Manufacturing Practices (GMP) requirements as part of the procedures for adding a new production line to a licensed facility, adding or replacing equipment, cancelling a production line

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

***With respect to factories affiliated with the General Authority for Industrial Development:**

1. The factory shall submit a request to the General Authority for Industrial Development, specifying the type of modification required, and attaching the relevant Layout

2-The General Authority for Industrial Development shall forward a copy of the factory's request to the General Administration for 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 Practice (GMP) requirements, in preparation for the issuance of the amended technical license of operation by the Egyptian Drug Authority, if deemed necessary.

***Note:**

In the case of factories affiliated with any of the following entities: (1) - the General Authority for Investment and Free Zones, whether operating in a free zone or an investment zone; or(2) - the Suez Canal Economic Zone, applications must be submitted directly to the General Administration for Factories Licensing at the Egyptian Drug Authority along with the required documents..

3-3.2 Verifying compliance with Good Manufacturing Practices (GMP) requirements as part of the procedures for approving any modification within the facility that does not involve changes to the driving power systems, such as amendments to the factory layout or modifications in the quality control laboratories

"This procedure shall be carried out through the General Administration for Factories Licensing"

1- The factory shall submit the following documents via the official electronic portal of the General Administration for Factories Licensing :
-Application form prepared for this purpose, signed by the Chairman of the Board of Directors or an authorized signatory, specifying the requested amendment.
- layout before and after the amendment.
-Authorization letter for the company's representative to deal with the Egyptian Drug Authority / Central Administration for Licensing of Pharmaceutical Establishments (General Administration for Factories Licensing) and to receive and submit all documents on behalf of the company. This authorization must be certified for signature authenticity by the bank of the authorized signatory, in accordance with the powers granted by the management.

2- A site licensing inspection shall be conducted by the Egyptian Drug Authority, and the factory's technical operating license shall be updated if deemed necessary.

3-4.1 Verifying compliance with **Good Storage Practices (GSP)** requirements for the **addition, modification, or cancellation of a warehouse within the factory premises,**

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

With respect to Factories Affiliated with the General Authority for Industrial Development (GAID):

1- The factory shall submit an application to the General Authority for Industrial Development, accompanied by the engineering drawings of the warehouse.

2 -The General Authority for Industrial Development shall forward a copy of the submitted application to the General Administration for Factories Licensing at the Egyptian Drug Authority.

3- A joint inspection shall be conducted by the Egyptian Drug Authority and the General Authority for Industrial Development to ensure compliance with Good Storage Practices (GSP) , in preparation for the issuance of the amended technical operating license by the Egyptian Drug Authority, if deemed necessary.

***Note:**

In the case of factories affiliated with any of the following entities: (1)- the General Authority for Investment and Free Zones, whether operating in a free zone or an investment zone; or (2) - the Suez Canal Economic Zone, applications must be submitted directly to the General Administration for Factories Licensing along with the required documents

3-4.2 Verifying compliance with **Good Storage Practices (GSP)** requirements for the **addition, modification, or cancellation of an accessory store (an off-site warehouse) affiliated with a licensed factory.**

"This procedure shall be carried out through the General Administration For Factories Licensing"

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

-Three (3) copies of the approved layout of the premises.

-Proof of possession of the premises: (A copy of the lease or ownership contract, provided that it is valid and notarized by the Real Estate Registry, or a court ruling. The warehouse must be licensed as a commercial activity and not residential or administrative. (Original documents must be presented for verification))

-Receipt evidencing payment of the inspection fee of 3 Egyptian Pounds.

-Original document from the Electricity Company proving the existence of an independent meter within the premises, indicating the meter number and the address of the premises, or the original document from the Electricity Company proving that electricity has been permanently connected until the meter is installed.

-Undertaking by the owner of the establishment not to sell through the warehouse and not to store any pharmaceutical products belonging to any other establishment.

- A Valid power of attorney granted to the company's representative to deal with the Egyptian Drug Authority, including receiving and submitting all company documents, provided that the authorization is certified by the bank as a signature authenticity certification of the duly authorized signatory.

2- The General Administration For Factories Licensing shall conduct the necessary licensing inspections to ensure compliance with Good Storage Practices (GSP).

3- The General Administration For Factories Licensing shall issue the accessory store License and update the technical operating license.

4- The factory shall pay the service fee amounting to EGP 20,000 (twenty thousand Egyptian pounds) upon receipt of the accessory store License.

3-5.1 Issuing **technical licenses of operation** for **Cosmetics Factories**

"This procedure shall be carried out through the General Administration For Factories Licensing"

1- The factory shall submit an application for the issuance of the **technical licenses of operation** using the designated form, duly signed by the Chairman of the Board of Directors or by the person authorized to sign on behalf of the factory, accompanied by the required documents, through the electronic portal of the General Administration For Factories Licensing, as follows:

-Documents Required for the Factory Manager:

-Curriculum Vitae (CV), including:

-Copies of academic qualification certificates (university degree and postgraduate studies, if any);

-Training certificates and certificates of professional experience.

-A copy of the Professional Syndicate Membership Card and the National Identification Number.

-A Declaration by the Responsible Manager, executed on the designated form and completed in the presence of a licensing Inspector from the General Administration for Factories Licensing.

-A copy of the **technical licenses of operation** issued by the General Authority for Industrial Development (GAID), if available.

- An Authorization appointing the company's representative to deal with the Egyptian Drug Authority / Central Administration of Pharmaceutical Institutions licensing (General Administration for Factories Licensing), including the submission, receipt, and delivery of all documents related to the company .The authorization shall be certified with bank signature authentication for the authorized signatory.

2-The General Administration for Factories Licensing shall review the submitted documents within **ten (10) working days** and notify the applicant of any documents required to be completed or supplemented.

3- In the event that the submitted documents are complete, the **technical licenses of operation** shall be issued within **ten (10) working days**. If the documents are not

completed by the factory within **fifteen (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 licenses of operation**

3-6 Adding or modifying any data in the factory's technical license of operation that does not require a licensing inspection

(For example, but not limited to: changing the name of an authorized representative - adding/removing a plot of land from the factory - changing the factory name/owner - transferring factory ownership - registering/changing the factory manager - verifying/renewing laboratory contracts)

"This procedure shall be carried out through the General Administration For Factories Licensing"

1- The factory shall submit an application for the amendment of the **technical licenses of operation** using the designated form, duly signed by the Chairman of the Board of Directors or the authorized signatory, and accompanied by all required documents according to the type of addition or amendment requested, as set out in the table below. This shall be submitted through the electronic portal of the General Administration for Factories Licensing, **as follows**

3-6-2 Procedure for Updating the Factory Address(Addition or Cancellation of a Land Plot)

-A copy of the updated Commercial Register (Original to be presented for verification).

-A copy of the updated Tax Card (Original to be presented for verification).

-A copy of the property possession deed / land allocation document (Original to be presented for verification).

-The Investment Gazette reflecting the amendment of the name (if applicable).

-A copy of the Operating License issued by the General Authority for Industrial Development

(if applicable).

-An Authorization appointing the company's representative to deal with the Egyptian Drug Authority / Central Administration of Pharmaceutical Institutions licensing (General Administration for Factories Licensing), duly authenticated with the bank signature verification of the person(s) entitled to sign in accordance with the company's management authorities.

3-6-3 Procedure for Changing the Factory / Owner Name

-A copy of the updated Commercial Register(Original to be presented for verification).

-A copy of the updated Tax Card(Original to be presented for verification).

-The Investment Gazette reflecting the amendment of the name (if applicable).

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

- An Authorization appointing the company's representative to deal with the Egyptian Drug Authority / Central Administration of Pharmaceutical Institutions licensing(General Administration for Factories Licensing), duly authenticated with the bank signature verification of the person(s) entitled to sign in accordance with the company's management authorities.

3-6-4 Procedure for Transferring Factory Ownership

-Notarized Sale Contract between the new owner and the seller.

- Copy of the Updated Commercial Register reflecting the factory sale.

- Copy of the Updated Tax Card.

-Copy of the Operating License issued by the General Authority for Industrial Development (if applicable).

- An Authorization appointing the company's representative to deal with the Egyptian Drug Authority / Central Administration for Licensing of Pharmaceutical Institutions (General Administration for Factories Licensing), duly authenticated with the bank signature verification of the authorized signatory.

2-The General Administration for Factories Licensing shall review the submitted documents within ten (10) working days and notify the applicant Of any documents required to be fulfilled.

1- In the event that the documents are fulfilled, the amended technical license of operation shall be issued within ten (10) working days, and in the event that the documents are not fulfilled by the factory within fifteen (15) working days, the application shall be archived.

3-7 Extracting certified copies of the technical operating license of a cosmetic manufacturing facility for documentation purposes abroad.

□"This procedure shall be carried out through the General Administration for Factories Licensing"

1- The factory shall submit an application for the issuance of a certified copy of the technical license of operation on the designated form, signed by the Chairman of the Board of Directors or the authorized signatory, accompanied by all required documents, through the electronic portal of the General Administration for Factories Licensing, as follows:

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

-Receipt evidencing payment of the service fee (EGP 1,000)

-A copy of an authorization addressed to the Egyptian Drug Authority / Central Administration of Pharmaceutical Institutions licensing (General Administration for Factories Licensing), authorizing the factory's designated representative to deal with the Egyptian Drug Authority, provided that the original authorization shall be reviewed upon receipt of the certified copy.

2- The General Administration for Factories Licensing shall review the submitted documents within ten (10) working days and notify the applicant of any documents required to be fulfilled.

3-In the event that the documents are fulfilled, a certified copy of technical license of operation shall be issued within seven (7) working days, and in the event that the documents are not fulfilled by the factory within fifteen (15) working days, the application shall be archived.

4- References

4-1 Law No. **127 of 1955** concerning the practice of the profession of pharmacy.

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.

4-4 Decision of the Chairman of the Egyptian Drug Authority No. **99 of 2021** regarding the disposition of pharmaceutical and medical supplies factories

4-5 Decision of the Chairman of the Egyptian Drug Authority No. **271 of 2021** regarding the requirements to be met for licensing storage premises affiliated with pharmaceutical institutions.

4-6 Decision of the Chairman of the Egyptian Drug Authority No. **272 of 2021** regarding the service fees for licensing storage premises affiliated with pharmaceutical institutions.

4-7 Decision of the Chairman of the Egyptian Drug Authority No. **273 of 2021** regarding the service fees for reviewing the engineering drawings of factories.

4- 8 Decision of the Chairman of the Egyptian Drug Authority No. **280 of 2021** regarding the service fees for certain services provided by the Central Administration for Licensing of Pharmaceutical Institutions.

4-9 Licensing requirements for cosmetic products factories in accordance with **ISO 22716**.

4-10 The Regulatory Guideline for the registration of managers of pharmaceutical and medical supplies factories.

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