Central Administration Of Pharmaceutical Institutions Licensing
General Administration Of Factories Licensing

Regulatory Guideline for the Procedures of

licensing procedures of plasma collection centers and plasma derivatives manufacturing factories , General Administration of Factories Licensing at the Egyptian Drug Authority.

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Table of content

1. Introduction

The General Administration of Factories Licensing at the Egyptian Drugs Authority is responsible for establishing a system and instructions for:

1-1 Plasma Collection Center

- Revising the layout of a plasma collection center.
- Conducting licensing inspection for a plasma collection center license.
- Issuing an operating license for a plasma collection center.
- Renewing an operating license for a plasma collection center.
- Conduct licensing inspection within the procedures of approving any modification to a licensed plasma collection center, for example, but not limited to modifying layout, adding an activity, adding a freezer, adding beds, adding donation devices).
- approving any modification to the operating license data of the Plasma Collection Center that does not require an inspection (including but not limited to: transfer of ownership of the center, change of center managers).
- Issuing certified typical copies of the operating license for a plasma collection center for documentation abroad.

1-2 Plasma derivatives manufacturing Factory

- Revising the layout of the plasma derivatives manufacturing Factory.
- Ensuring compliance with Good Manufacturing Practices (GMP) requirements within the procedures of the plasma derivatives manufacturing factory Licensing.
- Issuance of the technical operating license for the plasma derivatives manufacturing factory.
- Renewal of the technical operating license issued by the Egyptian Drug Authority for the plasma derivatives manufacturing factory.
- Ensuring compliance with Good Manufacturing Practices (GMP) requirements within the procedures of approving any modification to a licensed plasma derivatives manufacturing factory with a change in the power horse of machinery and equipment (for example, but not limited to: adding a new production line, adding a machine, replacing a machine, condemnation a machine, canceling a production line) or without a change in the power hourse of machinery and equipment (for example, but not limited to: modifying layout, Modification in quality control laboratories).
- Ensuring compliance with Good Storage and Distribution Practices (GSDP) requirments within the procedures of adding / modifying/cancelling a storage facility within premises of a licensed plasma derivatives manufacturing factory or adding / modifying/cancelling a accessory store affiliated to a licensed plasma derivatives manufacturing factory.

- Approval of any modification to the technical operating license data issued by the Egyptian Drug Authority for a plasma derivatives manufacturing factory that does not require Conducting licensing inspection (for example, but not limited to, changing the authorized representative, adding/cancellation a plot of land, changing the factory name, transferring factory ownership, or changing factory managers).
- Issuing certified typical copies of the operating license for a plasma collection center for documentation abroad.

2- Scope

The General Administration of Factories Licensing begin working from:-

2-1 Plasma Collection Center

- Receiving a request to revise the layout of the Plasma Collection Center until the approved layout is submitted.
- Receiving a request for Conducting licensing inspection of the plasma collection center license until the operating license is submitted.
- Receiving a request of renewing the operating license of the Plasma Collection Center until the renewed operating license is submitted.
- Receiving a request for Conducting licensing inspection within the steps to approve any modification to the licensed plasma collection center (for example, but not limited to: modifying an engineering drawing, adding an activity, adding a freezer, adding beds, adding donation devices) until the modification or modified operating license is delivered.
- Receiving a request to amend the operating license data of the Plasma Collection Center, which does not require Conducting licensing inspection (for example, but not limited to: transferring ownership of the center, changing the center's managers) until modified operating license is submitted.
- Receiving a request Issuing certified typical of the operating license of the plasma collection center for documentation abroad until the approved true copies are delivered.
- **2-2 Plasma Derivatives Manufacturing Factory**
- Receiving the request to review the layout of a plasma derivatives manufacturing factory until the approved layout are submitted.
- Receiving a request for Conducting licensing inspection for the plasma derivatives manufacturing factory license until the technical operating license is issued.
- Receiving the request to renew the technical operating license issued by the Egyptian Drug Authority for a plasma derivatives manufacturing factory until the renewed technical operating license is delivered.

- Receiving a request for Conducting licensing inspection as part of the steps to approve any modification to a licensed plasma derivatives manufacturing factory with a change in the the power horse of the machines and equipment (for example, but not limited to: adding a new production line, adding a machine, replacing a machine, condemnation of a machine, canceling a production line, or with no change in the power horse of the machines and equipment) (for example, but not limited to: modifying layout, modifying Laboratory quality control) until the technical operating license or proof of the modification is delivered.
- Receiving a request for Conducting licensing inspection for adding/modifying/canceling a store within the limits of a licensed plasma derivatives manufacturing factory, or adding/modifying/canceling a accessory store– affiliated to a licensed plasma derivatives manufacturing Factory, until the amended technical operating license and accessory store license, or proof of the amendment, are submitted.
- Receiving a request to amend the technical operating license data issued by the Egyptian Drug Authority for a plasma derivatives manufacturing factory, which does not require Conducting licensing inspection (for example, but not limited to changing the authorized person, annexing / canceling a plot of land, changing the name of the factory, transferring ownership of the factory, changing the managers of the factory) until receiving the modified technical operating license.
- Receiving a request Issuing certified typical copy of the technical operating license issued by the Egyptian Drug Authority for a plasma derivatives manufacturing factory for documentation abroad until the approved typical copies are delivered.

3-Definitions:

- Law: Law No. 8 of 2021 by issuing regulations for blood operations and collecting plasma to manufacture and export its derivatives.
- Plasma: It is a blood derivative, and includes therapeutic plasma and plasma collected for manufacturing purposes.
- Plasma derivatives: Biological products derived from components of human blood plasma, such as albumin, clotting factors, and other plasma derivatives.
- Intermediate plasma derivatives: One of the plasma derivatives that is partially separated and undergoes other manufacturing steps related to plasma concentrates (Bulk) and Finished Products.
- Finished plasma derivatives: biological products derived from finished blood plasma components in pharmaceutical dosage form.
- Plasma Collection Center: A center licensed to collect, store, analyze, or distribute plasma for manufacturing purposes.

- Plasma Exportation: Blood plasma exporting out of the Arab Republic of Egypt for manufacturing purposes and recovery in the form of plasma derivatives.
- Regular Donor: Every volunteer who donates plasma on a regular basis according to the medical rules.

- Unified Procurement Authority: It refers to the Egyptian Authority for Unified Procurement, Medical Supply and Managing the Medical Technology.
- Factory: A factory whose main purpose is to manufacture plasma derivatives for the purposes of the pharmaceutical industry. It may purchase plasma from centers licensed to collect plasma for the purpose of manufacturing, or from one of the companies whose main purpose is to sell, transport, and export and import plasma.
- Governing share: ownership of fifty percent or more of the company's capital, the ability to appoint a majority of the board members, or control in any way over the decisions issued by its board of directors or general assemblies.
- Blood Plasma Collection Unit for Therapeutic purpose: It is the place in which the donated plasma for therapeutic purpose is preserved, dispensed and where the necessary tests are conducted, in accordance with the national standards.

4- Working procedures for plasma collection centers

4-1 Revising of the layout of the plasma collection center

"This procedure shall be conducted by the General Administration of Factory Licensing at the Egyptian Drug Authority."

Documents / Procedures

1. The Center shall submit a request to review the layout on the form prepared for that purpose, signed by the Center's Director or the Chairman of the Board of Directors, attaching a copy of the layout (PDF) to be presented to the layout Review Committee on the electronic window of the General Administration of Factories Licensing.
2- The request will be examined and the service cosideration for the layout review service will be determined in accordance with the decision of the Chairman of the Egyptian Drug Authority No. 273 of 2021, and an email will be sent to notify of the service cosideration .

3- The center pays the service cosideration and submits the original payment receipt to the factories licensing window at the General Administration of Factories Licensing.
4- An appointment will be set for the layout review committee and an email will be sent to the center confirming the appointment.
5- The layout is revised in the presence of the center's representatives.

- **Hard copies shall be submitted to the layout Committee which are:**
  - The original, signed layout review request.

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

- Specifications of the engineering drawing consisting of two sheets:

Sheet 1: Shows the paths: Raw materials - Intermediate product - Waste disposal - personnel

Sheet 2: Shows the air classification and room pressure values (for air-classified areas)

- The sheet key must contain all the details of the sheet

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

- The line must be clear for all details of the layout.
- Spelling errors must be avoided.

6 - If there are no comments, the layout will be approved by the layout Review Committee, and a letter will be issued to the center confirming the approval of the layout, attached with a hard copy of the approved layout.

7- If the layout Review Committee has any comments, A letter of comments is sent to the center.

8-The Center submits a request to resubmit it to the layout Review Committee on the form prepared for this purpose immediately after the comments are fulfilled , via the electronic window of the General Administration of Factory Licensing, with a maximum of 3 completion committees. In the event that the comments are not completed, payment will be made for the service consideration to complete the revision.

9- The representative of the organization, institution, authority or owning company shall be act upon delegation to deal with the Egyptian Drug Authority / Central Administration of Pharmaceutical Institutions Licensing / General Administration of Factories Licensing to receive and deliver all documents related to the center, the authorization must be certified by a bank signature or the officially stamped Egyptian Eagle Seal (original for review).

4-2 Conducting a plasma collection center license until the plasma collection center operating license is submitted

“This procedure shall be conducted by the General Administration of Factories Licensing at the Egyptian Drug Authority.”

Documents / Procedures

1- The Center shall submit a license application on the form prepared for this purpose, signed by the Center Director or the Chairman of the Board of Directors. the data of the Center Director are attached to the application(medical doctor with experience in hematology), including their name, title, nationality, and address, attaching with the following documents:

• Official extracts of the following certificates: - Specialization certificate in various branches of medicine.

- All to be submitted via the electronic window of the General Administration of Factories Licensing.

A training and qualification certificate from the entity requesting the license, and the applicant must have practical experience in the relevant field, preferably at least two years in one or more institutions responsible for collecting, analyzing, preparing, storing, and distributing blood and its component. • A professional practice license issued by the relevant ministry.
• A copy of the national ID card.
• 4 personal photos.
• A copy of the Medical Syndicate membership card.
• Criminal Record
• Two copies of the layout of the plasma collection center to be licensed.
• The commercial register of the organization, institution, authority or company that owns the center, in application of legal Article 15 of the Executive Regulations of Law No. 8 of 2021
• The tax card of the organization, institution, authority or company that owns the center, in application of legal Article 15 of the Executive Regulations of Law No. 8 of 2021
• A copy of a manufacturing contract under the technical supervision of an international company specialized in the field of manufacturing plasma derivatives.
• A copy of the approving letter for the layout for plasma collection centers issued by the General Administration of Factory Licensing. (If any)
• Authorization for the representative of the organization, authority or owning company, to deal with the Egyptian Drug Authority/the Central Administration of Pharmaceutical Institutions Licensing / General Administration of Factories Licensing to receive and deliver all documents for the center, the authorization must be certified by bank signature or officially stamped Egyptian Eagle Seal (original for review).

(Provided that the original documents are submitted upon recieving the technical operating license.

- The license application form is obtained from the General Administration of Factory Licensing

2. The application will be examined within 7 working days, Ensuring payment of the prescribed charges of EGP 20,000. The center will be notified about the completion of the documents, the date of conducting the licensing inspection, or the documents that must be completed.
3. The licensing inspection is conducted to verify the implementation of the technical requirements and standards that must be applied , guided by the requirements of the World Health Organization (WHO), Pharmaceutical inspection Co-operation((PIC/s) & any updates concerning these requirments , within 30 working days of notifying the center of the completion of the document
4. In case that the center does not comply with the technical requirements and standards that must be applied , comments must be fulfilled and the committee members of licensing inspection fulfillment committee are determined by the members of the final licensing inspection committee during the licensing inspection, and a letter of comments is issued to the center

5. After the Center has fulfilled the comments of the final Inspection Committee, the center must submit a request to conduct the licensing inspection of fulfill comments, and the licensing inspection is conducted within 30 working days.
6. If the center conforms to the technical requirements and standards that must be applied , the center should head to the window of the General Administration of Factories Licensing to request a supply order before paying the charges in the treasury of the Egyptian Drug Authority.
7-The plasma collection center operating license is issued within 15 working days by decision of the Chairman of the Egyptian Drug Authority after ensuring payment of the prescribed charges of seventy-five thousand pounds for the first technical operating license.
The center technical operating license is valid for 3 years.
4-3 Procedure for renewing the technical operating license of the plasma collection center
“This procedure shall be conducted by the General Administration of Factory Licensing at the Egyptian Drug Authority”.

Documents / Procedures

1.The same previous steps from (1) to (6) are followed in procedure (4-2).
2. A renewed technical operating license for the plasma collection center will be issued within 15 working days by decision of the Chairman of the Egyptian Drug Authority after ensuring payment of the prescribed charges of thirty-five thousand pounds to renew the technical operating license.
The center's technical operating license will be valid for 3 years.
The Center shall submit a request to renew the technical operating license no later than six months before the expiration of the license period.

4-4 - Conduct an inspection within the procedures of approving any modification to the licensed plasma collection center (for example, but not limited to: modifying latout, adding an activity, adding a freezer, adding beds, adding donation devices)
"This procedure shall be carried out through the General Administration of Factories Licensing at the Egyptian Drug Authority"

Documents / Procedures

1- The Center shall submit a request stating the type of modification required, signed by the Center Director or the Chairman of the Board of Directors, attaching with the layout, if necessary, via the electronic window of the General Administration of Factories Licensing
2- The application will be examined within 7 working days, and the center will be notified about the completion of the documents and the date of the licensing inspection (if the modification requires a licensing inspection) or the documents that must be fulfilled.
3-If the documents are fulfilled, an inspection will be conducted if the modification requires a licensing inspection to verify the implementation of the technical requirements and standards that must be established within 30 working days of notifying the center indicating that the documents have been complete
4- If the center does not comply with the technical requirements and standards that must be fulfilled , the comments to be applied must be determined & the the members of the meeting inspection committee are determined by the members of the licensing inspection committee during the visit, and a letter of comments is issued to the center.
5-Once the Center has completed the comments of the Inspection Committee, the Center shall submit a request to conduct a licensing inspection and this licensing inspection shall be conducted within 30 working days.
6- If the center complies with the technical requirements and standards that must be applied, the technical operating license of the plasma collection center - including the required modification- will be updated within 15 working days if the modification requires updating the technical operating license, or the center will be given information indicating the modification.
7- The representative of the organization, institution, authority or owning company shall deal with the Egyptian Drug Authority / Central Administration of Pharmaceutical Institutions Licensing / General Administration for Factories Licensing to receive and deliver all documents related to the center, the authorization must be certified by a bank signature or the officially stamped Egyptian Eagle Seal (original for review).

4-5 Modifying the plasma collection center operating licensing data, with no need of conducting a licensing inspection (for example but not limited, Transfer of ownership of the center, change of center managers

"This procedure shall be conducted by the General Administration of Factories Licensing at the Egyptian Drug Authority."

Documents / Procedures

- The center submits an application mentioning the type of modification, signed by the Center Director or the Chairman of the Board of Directors certified by a bank signature or the officially stamped Egyptian Eagle Seal, attached with the required document, via the electronic window of the General Administration of Factories Licensing (provided that The original documents must be submitted upon receiving the center's technical operating license)
- The application will be examined and documents should be reviewed within 7 working days.
  -If the documents are fulfilled, the plasma collection center's technical operating license will be updated including the required modification within 15 working days.
  -If the documents are not fulfilled, the center will be notified about the documents that must be fulfilled, and if the documents are not fulfilled by the center within 15 working days, the application will be archived.
  -The representative of the organization, institution, authority or owning company shall deal with the Egyptian Drug Authority / Central Administration of Pharmaceutical Institutions Licensing General Administration of Factories Licensing Licensing to receive and deliver all documents related to the center, the authorization must be certified by a bank signature or the officially stamped Egyptian Eagle Seal (original for review).

a- Documents required to be submitted in case of transferring ownership of the center

1- Certified sale contract between the new owner and the seller (original for review).
2- A copy of the modified commercial register proving the transfer of ownership (the original for review).
3- A copy of the modified tax card (original for review).

B. Documents required in case of change of center manager

1- Official documents of the following certificates:
- Specialization certificate in various medical branches.
- A training and qualification certificate from the entity requesting the license , He must have a practical experience in the relevant field, preferably not less than two years in one or more of institutions responsible for collecting, analyzing, preparing, storing and distributing blood and its components.
- Professional license issued by the competent ministry.

2- A copy of the national ID card.
3- 4 personal photos.
4- A copy of the Doctors Syndicate membership card.
5-the original document of the criminal record.
6- A CV with at least two years of experience in the field of hematology.

C- Documents required in case of a change in operations manager, quality assurance, quality control

1- A CV with experience related to the field of hematology.

4-6 Procedure for issuing a typical copy of the plasma collection center's operating license

"This procedure shall be conducted by the General Administration of Factories Licensing at the Egyptian Drug Authority."

Documents / Procedures

The Center shall submit a request to obtain a typical copy of the Center's technical operating license on the form prepared for this purpose, signed by the Center's Director or Chairman of the Board of Directors, attaching the following documents:

• A copy of the center's latest technical operating license issued by the General Administration of Factories Licensing.
• A receipt for payment for the service (1,000 pounds), where the center representative heads to the window of the General Administration of Factory Licensing to request a supply order before paying the charges in the treasury of the Egyptian Drug Authority.
• Delegating the representative of the organization, institution, authority, or owner company to deal with the Egyptian Drug Authority, the Central Administration of Pharmaceutical Institutions Licensing / the General Administration for Factories Licensing, to receive and deliver all documents related to the center, and the delegation shall be approved by the validity of a bank signature or the officially stamped Egyptian Eagle Seal (the original for review).

This is done via the electronic window of the General Administration of Factories Licensing (provided that the original documents are submitted upon receiving the typical copy of the center's technical operating license).

2- The request and documents will be reviewed within 3 working days.
3- If the documents are fulfilled, an typical copy of the center's technical operating license will be issued within 7 working days. If the documents are not completed, the center will be notified about the documents that must be completed. If the documents are not completed by the center within 15 working days, the application will be archived.

5- General Requirements

1-The license is granted to any government agencies or private companies in which the country, any ministry, or any public law person, contributes to it with controlling stake, provided that the centers are linked to a manufacturing contract and under the technical supervision of an international company specialized in the field of manufacturing blood plasma derivatives.
2-For licensing Plasma collection centers owned by other private law persons, it is required that the license applicant must be a licensed factory owner within the Arab Republic of Egypt in accordance with the provisions of this law.
3- According to the law, the primary activity of the center is the collection of plasma from donors for the purpose of manufacturing, and it can carry out one of the activities related to plasma collection, including analysis and storage.
4- Full compliance with the technical requirements and standards determined by the Egyptian Drug Authority, guided by the standards approved by international organizations.
5- The instructions and requirements related to civil protection at the facility ,including fire alarm systems, water tanks, storage security, electrical work in accordance with the Egyptian Code, and generator room security must be complied
6- Availability of a backup generator to operate devices in case of a power outage.
7-Government agencies are exempted from paying charges.

5-1 Cases Requiring Administrative Closure

1- In the event of a violation of any of the licensing and inspection conditions, as determined by the relevant committees, the Egyptian Drug Authority has the right to suspend the violating activity. The Authority may then grant a grace period to rectify the situation. If the remissness in Providing the technical requirements continues, the activity license will be cancelled.
2- The existence of blood plasma collection center, exercising the activity, without the necessary licenses.
3- Managing a blood plasma collection center without the supervision of a human physician.

4- If the license applicant submits a request to the issuing authority to suspend the activity for a specific period, and the authority approves the request.

- Closure becomes mandatory if the violation is not rectified within six months of the date of the issuing the closure decision and notifying of the violation committed, In case of a repeat offense, the closure becomes mandatory.
- The closure period must not be less than three months and not exceed one full year, except in the second case, in which case the closure will be until the licenses are obtained.

5-2 Cases Requiring License Cancellation

1- In case of breaching of the technical requirements for licensing or inspection, and has not been rectified within six months of the date of notification of being notified of the breach.

2- Operating the center without the supervision of a human physician.

3- If it is found that the blood plasma collection center has not been operating for a full calendar year.

6. Working procedures for plasma derivatives manufacturing Factories.

6-1 conducting a revision of the layout of plasma derivatives manufacturing Factories

1- The factory submits a request to review the layout on the form prepared for that purpose, signed by the Chairman of the Board of Directors, attaching a copy of the layout (PDF) to be presented to the layout review committee via the Electronic window of the General Administration of Factory Licensing.

2. The application will be examined and the charges for the layout revising service will be determined in accordance with the decision of the Chairman of the Egyptian Drug Authority No. 273 of 2021, and an email will be sent to the factory, to notify about the service charges.

3- The factory pays for the service and delivers the original payment receipt to the window of the General Administration of Factory Licensing.

4- A date is set for the layout revising committee and an email is sent to the factory notifying about the appointment.

5- The layout is reviewed in the presence of the factory representatives.

Hard copies are brought to be presented to the layout Committee to be as following:

-The original signed request to review the layout.

-Two hard copies of the layout, each copy to be attached in an envelope file

- Specifications of the layout consisting of two sheets.

Sheet 1: Shows the flows of : Raw materials - Intermediate product - Waste disposal & personnel

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

- The sheet key must contain all the details of the sheet (The Company name, Color coding, key for any abbreviations and Activity of the production line)

-The line must be clear concerning all details of the layout..

- Spelling errors must be avoided.

6- If there are no comments, the layout is approved by the layout Review Committee, and a letter is issued to the factory confirming the approval of the layout., attaching a hard copy of the approved layout.

7- If the layout Review Committee has any comments, a letter containig the comments will be sent to the factory.

8- The factory resubmits a request to the layout Review Committee on the form prepared for this purpose immediately after the comments are fulfilled, via the electronic window of the General Administration of Factories Licensing with a maximum of 3 completion committees. In case that the comments are not fulfilled, payment will be made for the service to complete the reviews.

9- The factory representative is authorized to deal with the Egyptian Drug Authority, Central Administration for Licensing of Pharmaceutical Establishments / General Administration of Factories Licensing, to receive and deliver all documents related to the factory, and the authorization shall be approved by bank signature or Officially Stamped Egyptian Eagle seal (the original for review).

6-2 Ensuring compliance with Good Manufacturing Practices (GMP) within the procedures of Plasma Derivatives Manufacturing Factory Licensing.

"This procedure shall be carried out by the General Administration for Factories Licensing at the Egyptian Drug Authority in cooperation with the General Industrial Development Authority and coordination with the Unified Procurement Authority"

Documents / Procedures

1. The factory submits a license application to the General Industrial Development Authority, attaching the following documents.

• A copy of the license holder's national ID card (original for review).
• Original valid criminal record, confirming the license holder has no prior convictions, to be presented to the General Administration for Factories Licensing - Egyptian Drug Authority.
• Original birth certificate or an official copy for the license holder.
• An layout of the site to be licensed, consisting of one original and two copies, stamped with the seal of a consulting engineer, and shown the following: Personal flow, material flow, room classes, differential pressure.
• Copy of Investment Gazette (Original for review)
• Copy of Land Allocation Decision (Original for review)
• Copy of Commercial Registration (Original for review)
• Copy of Tax Card (Original for review)

2. The Industrial Development Authority sends a copy of the application submitted by the factory to the General Administration for Factories Licensing.

3. The Egyptian Drug Authority sends a letter to the Unified Procurement Authority (UPA) requesting its opinion on the procedures for the technical operating licensing of the plasma derivatives manufacturing Factory. The Unified Purchasing Authority responds to the Egyptian Drug Authority on whether or not to proceed with the procedures for licensing the plasma derivatives manufacturing Factory within 3 working days

. In case there is no response, it is considered an approval to proceed the procedures
4- The application will be reviewed within 7 working days, provided the required charges of forty thousand Egyptian pounds is paid.
5- If the required documents are not fulfilled , the factory will be notified about the documents to be fulfilled.
6- If the required documents are fulfilled, a joint licensing inspection will be conducted cosisting of the Egyptian Drug Authority and the Industrial Development Authority to verify compliance with the necessary technical requirements and standards within 30 working days.
7. In case that the center does not comply with the technical requirements and standards that must be applied , comments must be fulfilled and the committee members of licensing inspection fulfillment committee are determined by the members of the final licensing inspection committee during the licensing inspection visit , and the General Industrial Development Authority shall sent a letter of comments to the factory.
8- Once the factory has completed the comments of the final licensing inspection committee, the factory submits a request to the General Industrial Development Authority to conduct a licensing inspection to fulfill the comments, and the licensing inspection to fulfill the comments is conducted within 30 working days.

6-3 Procedure for Issuing a Technical Operating License for a Plasma Derivatives Manufacturing Factory

"This procedure shall be carried out by the General Administration of Factories Licensing at the Egyptian Drug Authority"

Documents / Procedures
1-The factory shall submit application to obtain a technical operating license on the form prepared for this purpose, signed by the Chairman of the Board of Directors or his authorized representative, attaching the following documents:
• Documents for managers according to the type of factory, as shown in the regulatory guide for registering managers of pharmaceutical and supplies factories.
• A copy of the operating license issued by the General Authority for Industrial Development. (If any)
• Authorizing the factory representative to deal with the Egyptian Drug Authority, the Central Administration of Pharmaceutical Institutions Licensing/General Administration for Factories Licensing, to receive and deliver all documents related to the factory, and the authorization must be certified by a valid bank signature or an eagle seal (for review).
This is done via the electronic window of the General Administration of Factories Licensing (provided that the original documents are submitted upon receiving the factory's technical operating license).
2-The application will be examined and documents reviewed within 7 working days. The factory will be notified about the fulfilled

documents and will head the window of the General Administration of Factories Licensing to request a supply order before paying the charges to the Egyptian Drug Authority treasury or with the documents that must be completed.

3-If the documents are fulfilled, a technical operating license for the plasma derivatives manufacturing factory will be issued within 15 working days in accordance with the decision of the Chairman of the Egyptian Drug Authority after ensuring of payment of the prescribed charges of two hundred thousand pounds for the technical operating license for the first time. The technical operating license for the factory will be valid for a period of 5 years.

4-If the documents are not fulfilled by the factory within 15 working days, the application will be archived.

6-4 Procedure for renewing the technical operating license for the plasma derivatives manufacturing Factory

"This procedure shall be carried out by the General Administration for Factories Licensing at the Egyptian Drug Authority"

Documents / Procedures

1-The same previous steps are followed from(1) to (8) in procedure (5-2) and from (1) to (2) in procedure (5-3).

2. The renewed technical operating license for the plasma derivatives manufacturing plant will be issued within 15 working days in accordance with the decision of the Chairman of the Egyptian Drug Authority after ensuring payment of the prescribed charges of one hundred thousand pounds to renew the technical operating license, and the technical operating license for the factory will be valid for a period of 5 years.

3-The factory shall submit application to renew the technical operating license no later than six months before the end of the license period.

6-5 Ensuring compliance with Good Manufacturing Practices (GMP) within the procedures of approving any modification of the licensed plasma derivatives manufacturing factory with or without a change in the power horse of the machines and equipment

First: With a change in the power horse of machines and equipment (for example but not limited to): adding a new production line, adding a machine, replacing a machine, canceling a production line)

"This procedure shall be carried out by the General Administration of Factories Licensing at the Egyptian Drug Authority in partnership with the General Industrial Development Authority "

Documents / Procedures

1. The factory submits an application to the Industrial Development Authority (attaching the layout , if necessary).

2- The General Authority for Industrial Development sends a copy of the application submitted

by the factory to the General Administration of Factories Licensing.
3- A joint licensing inspection is conducted consisting of the Egyptian Drug Authority and the General Industrial Development Authority to verify compliance with the required technical specifications and standards within 30 working days.
4-If the factory does not comply with the technical requirements and standards that must be applied , the comments that must be fulfilled and the members of the meeting inspection committee shall be determined by the members of the inspection committee during the inspection, and the General Industrial Development Authority shall send a letter of comments to the factory.
5- Once the factory has fulfilled the licensing inspection committee's comments, the factory submits a request to the General Industrial Development Authority to conduct a licensing inspection to complete the comments, and this licensing inspection will be conducted within 30 working days.
6- If the factory complies with the technical requirements and standards that must be met, the technical operating license of the plasma derivatives manufacturing factory will be updated, including the required modification, within 15 working days if the modification requires updating the technical operating license, after ensuring that the prescribed charges is paid, if any. The factory will head the window of the General Administration of Factories Licensing to request a supply order before paying the charges in the treasury of the Egyptian Drug Authority.
7-The factory representative is authorized to deal with the Egyptian Drug Authority, Central Administration for Licensing of Pharmaceutical Institutions / General Administration for Factories Licensing, to receive and deliver all documents related to the factory , and the authorization must be certified by a valid bank signature or an eagle seal (for review).

Second: With no change in the power horse of the machinery and equipment (for example, but not limited to:) modification of an layout , modification of the quality control laboratories .

"This procedure is carried out through the General Administration for Factories Licensing at the Egyptian Drug Authority".

Documents / Procedures

1-The factory submits an application specifying the type of modification required, signed by the Chairman of the Board of directors or their authorization holder (attaching the layout before and after the modification), via the electronic window of the General Administration of Factories Licensing.
2- The application will be reviewed within 7 working days, and the factory will be notified of the fulfilled of the documents and the date of the licensing inspection, if required, or of any additional documents that must be fulfilled.
3-A licensing inspection will be carried out if the modification requires a licensing inspection to verify the implementation of the technical requirements and standards that must be applied within 30 working days from notifying the factory that the documents is fulfilled.

4- If the factory does not comply with the technical requirements and standards that must be applied , comments must be fulfilled and the committee members of licensing inspection fulfillment committee are determined by the members of the final licensing inspection committee during the licensing inspection visit, and a letter of comments is issued to the factory.

5-Once the factory has fulfilled the licensing inspection committee's comments, the factory submits a request to conduct a licensing inspection to complete the comments, and this licensing inspection will be conducted within 30 working days.

6-If the factory complies with the technical requirements and standards that must be applied, the technical operating license of the plasma derivatives manufacturing factory will be updated, including the required modification, within 15 working days if the modification requires updating the technical operating license, or the factory will be given evidence of the modification.

7-The factory representative is authorized to deal with the Egyptian Drug Authority, Central Administration of Pharmaceutical Institution Licensing / General Administration of Factories Licensing , to receive and deliver all documents related to the factory, and the authorization must be certified by a valid bank signature or an eagle seal (for review).

6-6 Ensuring compliance with Good Storage and Distribution Practices (GSDP) requirements within the procedures of adding, modifying, or canceling a warehouse within the permises of a licensed plasma derivatives manufacturing factory, or adding, modifying, or canceling accessory store affiliated to a licensed plasma derivatives manufacturing Factory.

First: Adding, modifying, or canceling a warehouse within the boundaries of a licensed plasma derivatives manufacturing factory.

"This procedure shall be carried out through General Administration of Factories Licensing at the Egyptian Drug Authority in partnership with The Genral Industrial Development Autority.

Documents / Procedures

1- The factory submits an application to the Industrial Development Authority, attaching the warehouse layout.

2- The Genral Industrial Development Autority sends a copy of the application submitted by the factory to the General Administration of Factories Licensing

3-A joint licensing inspection is conducted by the Egyptian Drug Authority and The Genral Industrial Development Autority to ensure compliance with GSDP requirements within 30 working days.

4-In case of the warehouse does not comply with the requirements of GSDP that must be applied , the comments that must be fulfilled and the committee members of licensing inspection fulfillment committee are determined by the members of the final licensing inspection committee during the licensing inspection visit , and the General Industrial Development Authority shall sent a letter of comments to the factory.

5- Once the factory has fulfilled the licensing inspection committee's comments of the warehouse , the factory submits a request to the General Industrial Development Authority to conduct a licensing inspection to fulfill the comments, and this licensing inspection will be conducted.

6-If the factory complies with the requirements of GSDP that must be applied , the technical operating license of the plasma derivatives manufacturing factory will be updated, including the required modification, within 15 working days in case that the modification requires updating the technical operating license.

5- The factory representative is authorized to deal with the Egyptian Drug Authority, Central Administration of Pharmaceutical Institutions licensing / General Administration for Licensing of Factories, to receive and deliver all documents related to the factory. and the authorization must be certified by a valid bank signature or an eagle seal (the original copy for review).

Second: **<u>adding, modifying, or canceling a accessory store associated to a licensed plasma derivatives manufacturing Factory</u>**

"This procedure shall be carried out through the General Administration of Factories Licensing at the Egyptian Drug "

<u>Documents / Procedures</u>
1-The factory submits an application for accessory store license, signed by the Chairman of the Board of directors or his authorized representative ,attaching the following documents:
• 3 approved copies of the site layout
• Evidence of ownership of the premises (a copy of a rental or ownership contract) provided that it is valid and notarized by the real estate registry office or court ruling, provided that the accessory store location is licensed as a commercial activity and not residential or administrative (original for review).
• A receipt for payment of the licensing inspection charges of 3 Egyptian pounds.
• An original document from the electricity company stating that there is an independent electric meter inside the premise, provided that the electric meter number and accessory store address are proven in the document, or an original document is brought from the electricity company stating that the electrical current has been connected permanently until the electric meter is installed.

• A commitment from the owner of the establishment not to sell through the accessory storage facility and not to store any pharmaceutical products belonging to any other establishment.
Authorization of the factory representative to deal with the Egyptian Drug Authority, Central Administration Pharmaceutical Institution Licensing / General Administration of Factories Licensing, to receive and deliver all documents related to the factory, and the authorization must be certified by a valid bank signature or an eagle seal (for review).

2- The application will be reviewed within 7 working days, and the factory will be notified about fulfillment of the documents and the date of the licensing inspection, or of any documents that must be fulfilled.
3-If the documents are fulfilled, an inspection will be conducted to verify compliance with Good Storage Practices (GSDP) requirements within 30 working days.
4-In case of the storage facility does not comply with the requirements for GSDP that must be met, the comments that must be fulfilled and the formation of the members of the meeting inspection committee are determined by the members of the licensing inspection committee during the licensing inspection visit , and a letter of comments is issued to the factory.
5-Once the factory has fulfilled the licensing inspection committee's comments, the factory submits a request to the General Industrial Development Authority to conduct an inspection to complete the comments, and this licensing inspection will be conducted within 30 working days.

6-If the factory complies with the requirements for GSDP that must be applied, the technical operating license of the plasma derivatives manufacturing factory will be updated, including the required modification, and a accessory store license will be issued within 15 working days.
7-The factory representative heads the window of the General Administration of Factories Licensing to request a supply order before paying the charges to the Egyptian Drug Authority treasury, then paying for the service amounting to twenty thousand pounds to license the accessory store upon receiving of the accessory store license.

6-7 Modification of the technical operating license data for the plasma derivatives manufacturing factory, which does not require a licensing inspection, for example, but not limited to: changing the name of the authorization holder, adding / canceling a plot of land for the factory, changing the name of the factory, transferring ownership of the site, registering / changing the site managers)

"This procedure shall be carried out through the General Administration of Factory Licensing at the Egyptian Drug Authority in partnership "

Documents / Procedures

1-The factory shall submit a request to modify the technical operating license on the form prepared for that purpose , signed by the Chairman of the Board of Directors or his legal representative or authorized representative and approved with the validity of a bank signature or

an eagle seal, attaching the required documents, via the electronic window of the General Administration of Factory Licensing (provided that the original documents are submitted upon receiving the technical operating license of the factory.
2-The application and documents are reviewed within 7 working days.
3-If the documents are fulfilled, the technical operating license for the plasma derivatives manufacturing factory will be updated, including the required modification , within 15 working days.
4- If the documents are not fulfilled, the factory will be notified about the documents that must be fulfilled, and if the documents are not fulfilled by the factory within 15 working days, the request will be archived.
5- The factory representative is authorized to deal with the Egyptian Drug Authority, Central Administration Pharmaceutical Institution Licensing / General Administration of Factories Licensing, to receive and deliver all documents related to the factory. The authorization must be certified by bank signature or the official seal (original for review).

a- Documents required to be submitted in case that the name of the authorized person is changed

1- Personal documents of the authorized representative (new license holder) which are:
-A copy of the national ID card (original for review).
-A valid original criminal record, stating that there are no previous convictions, is presented to the General Administration of Factories Licensing - Egyptian Drug Authority.
-Original birth certificate or an official copy of it
2-A copy of the commercial register (original for review

- The authorized person (license holder) (is the Chairman of the Board of Directors of the company that owns the factory and has the authority to sign, according to the rights mentioned in the commercial register or is authorized by himself under an official authorization signed by the Chairman of the Board of Directors and approved by a bank signature or an eagle seal.

b- Documents required to be submitted in case of adding / canceling a plot of land for the factory

1. A copy of the amended commercial register (original for review).
2. A copy of the amended tax card (original for review).
3- A copy of premises ownership Proof / land allocation document (original for review).
4- Investment Gazette showing name change, (if applicable).
5- a copy of the operating license issued by the General Industrial Development Authority,(if any).

C- Documents required to be submitted in case of changing the factory name

1. A copy of the amended commercial register (original for review).
2. A copy of the amended tax card (original for review).
3- Investment Gazette showing name change, if applicable).

4- a copy of the operating license issued by the General Authority for Industrial Development, if any).

D. Documents Required in Case of Factory Ownership Transfer

1-A notarized sales contract between the new owner and the seller (original for review)
2-A copy of the amended commercial register proving the transfer of ownership (original for review).
3-A copy of the amended tax card (original for review).
4-A copy of the operating license issued by the General Industrial Development Authority ,(if any).

E-Documents required to be submitted in case of registration / changing of factory managers

Documents for managers according to the type of factory- as shown in the regulatory guide for registering managers of pharmaceutical and supplies factories-

6-8 Procedure for extracting an Typical copy of the technical operating license for the plasma derivatives manufacturing factory

"This procedure shall be carried out through the General Administration of Factories Licensing at the Egyptian Drug "

Documents / Procedures
1-The factory shall submit a request to obtain an Typical copy of the factory's technical operating license on the form prepared for that, signed by the factory manager, the chairman of the board of directors, his legal representative, or his authorized representative, attaching the following documents:
• A copy of the latest technical operating license for the factory issued by the General Administration of Factories Licensing.
• A receipt for payment of the service charges (1000 EGP). The factory must head the window of the General Administration of Factories Licensing to request a supply order before paying the chargess at the Egyptian Drug Authority's treasury.
• Authorization of the representative of the owning organization, institution, authority, or company to deal with the Egyptian Drug Authority (Central Administration of Pharmaceutical Institutions Licensing /General Administration of Factories Licensing) to receive and deliver all documents related to the center. The authorization must be certified with a bank signature or the official seal (original for review).
This is done via the electronic window of the General Administration of Factories Licensing (provided that the original documents are submitted upon receiving of an exact copy of the

factory's technical operating license).
2-The application and documents are reviewed within 3 working days.
3-If the documents are fulfilled, a typical copy of the factory's technical operating license will be issued within 7 working days
4- If the documents are not fulfilled, the factory will be notified about the documents that must be completed, and if the documents are not fulfilled by the factory within 15 working days, the application will be archived.

6-General Requirements for Plasma Derivatives Manufacturing Factory:

1. Full compliance with the technical requirements and standards determined by the Egyptian Drug Authority, guided by the standards approved by international organizations.
2. Government agencies are exempt from paying charges.

7-1 Cases Requiring Administrative Closure

1- In case of violation of any of the licensing and inspection conditions, as determined by the relevant committees, the Egyptian Drug Authority has the right to suspend the violation activity. The Authority may then grant a grace period to rectify the situation. If the remissness in fulfill the technical requirements continues, the activity license will be cancelled.
2- The existence of a plasma derivatives manufacturing factory, engaged in the manufacturing activity, without the necessary licenses.
3- The operation of a plasma derivatives manufacturing factory without presence of a site manager or a quality control manager.

4- If the license applicant submits a request to the issuing authority to suspend the activity for a specific period, and the authority approves the request.
   - Closure becomes mandatory if the violation is not rectified within six months of the date of the issuing the closure decision and notifying him about the violation committed, In case of a repeatitive offense, closure becomes mandatory.
   - The closure period must not be less than three months and not exceed one full year, except in the second case, in which case the closure will be until the licenses are obtained.

7-2 Cases Requiring License Cancellation

1- In case of a breaching of the technical requirements for licensing or inspection, if the violation is not rectified within six months of the date of of the violation.
2- Operating the factory without a factory manager or a quality control manager.
3- If it is found that the factory has not been operating for a full calendar year.

8-References:

8-1 Law No. 8 of 2021 Issuing the Law Regulating Blood Transfusions and Plasma Collection for the Manufacture and Export of its Derivatives.
8-2 Prime Ministerial Decree No. 2603 of 2021 Issuing the Executive Regulations of the Law Regulating Blood Transfusions and Plasma Collection for the Manufacture and Export of its Derivatives, issued by Law No. 8 of 2021.
8-3 Law No. 127 of 1955 concerning the practice of the pharmacy profession.
8-4 Law No. 151 of 2019 concerning the establishment of the Egyptian Drug Authority and its executive regulations.
8-5 Decision No. 271 of 2021,regarding the requirements for licensing accessory store affiliated with Pharmaceutical Institutions.
8-6 Decision No. 272 of 2021 issued by the Chairman of the Egyptian Drug Authority concerning the chargess for services related to licensing accessory store affiliated with Pharmaceutical Institutions.
8-7 Decision No. 273 of 2021 issued by the Chairman of the Egyptian Drug Authority concerning the chargess for services related to reviewing layout for factories.