# Clearance Conditions and Requirements

## Volume 1.6

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# Clearance Conditions and Requirements

Operation Sector

Saudi Food and Drug Authority

For more information, please visit the website:

https://www.sfda.gov.sa/AR/DRUG/DRUG_REG/Pages/drug_reg.aspx

For inquiries:

Drug.Comments@sfda.gov.sa

Or call 19999

**Vision:**

To be the leading globally regulatory authority based on scientific basics to enhance and protect the public health.

**Mission:**

Protecting the society through regulations and controlling structure to ensure the safety of food, drug, medical devices, cosmetics, pesticides and fodders.

# Questioned Documentation

| Volume | Date | Publisher | Notes |
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| 1 | 20/8/2015 | Executive Directorate of Inspection and Law Enforcement | Updated<br>(In this version, clearance and exports were separated from imports besides combining the human and veterinary drugs.) |
| 1.1 | 6/10/2016 | Executive Directorate of Inspection and Law Enforcement | Updated |
| 1.2 | 21/12/2017 | Executive Directorate of Inspection and Law Enforcement | Updated |
| 1.3 | 19/8/2018 | Executive Directorate of Inspection and Law Enforcement | Updated |
| 1.4 | 4/2/2019 | Clearance department and ports support (operation sector) | Updated<br>) In this version, export requirements were transferred to the Import and Export Code. ( |
| 1.5 | 18/11/2020 | Clearance department and ports support (operation sector) | Updated |
| 1.6 | 4/2/2021 | Regulatory affairs department.<br>Standards setting departments. | Updated |

**The updated information in this version (1.6) is:**

| Content | The updated info |
|---|---|
| General Conditions | Removing the price printing condition for products, which are priced by the Authority. |

## Table of Content:

# 1.Defenitions

- **Authority**: Saudi Food and Drug Authority (SFDA).
- **Sector**: Operation Sector.
- **Inspectors**: Operation Sector Inspectors at SFDA.
- **Ports**: Customs Ports in Saudi Arabia that allow supplying products that are subjected to the control of the Operation Sector.
- **Clearance**: Approval issued by Operation Sector to customs permitting the entry of products into Saudi Arabia.
- **IBRCS**: An electronic system in which the permission of import and clearance is issued, also it is used to report the locally manufactured batches for the human, herbal, health and veterinary products.
- **Clearance (Fash, Tabadl)) platform:** An electronic system to connect between the SFDA and Customs authority to complete the clearance applications
- **Importer**: The agent or importer who supplied the external shipments.
- **Beneficiary**: The final recipient of the incoming shipments.
- **Unregistered Drug or Products**: A drug/ product that does not have a valid certificate of pharmaceutical product (CPP) by SFDA.
- **Registered Drug or Products**: A drug/ product that has a valid certificate of pharmaceutical product (CPP) by SFDA.
- **Listed Drug or Products**: A drug/ product that has a valid certificate of inclusion by SFDA.
- **Registered Veterinary Products**: A veterinary drug, products, pesticide, and disinfectant that have a valid certificate of pharmaceutical product (CPP) by SFDA.
- **Unregistered Veterinary Products**: A veterinary drug, products, pesticide, and disinfectant that do not have a valid certificate of pharmaceutical product (CPP) by SFDA.
- **Registered Drug or Products Samples**: Used for demonstration purposes to health practitioners.
- **Samples:** Supplied in purpose of registration or analysis at SFDA, or samples submitted to government tenders for a product which there is no substitute registered by SFDA.
- **Standard Materials**: Supplied in purpose of analysis and registration by SFDA.
- **Educational Products**: Used for educational purpose and do not contain any active substances.
- **Raw Medical Plants**: Used for medical purposes and in raw form.
- **Compassionate drug**: Used before its registration in any supervisory health authority to treat some critical cases, and it is approved to be imported according to the controls and conditions.

## 2.General Condition:

- The importer shall have a licensed warehouse and valid warehouse manager from the operations sector in SFDA that allowed to practice storing the product to be cleared.
- The clearance application shall be submitted electronically to the Sector Office at the Port of Arrival via the IBRCS clearance system as well as Tabadl clearance platform.
- The supply of registered or listed drug and product shall be in accordance with the specifications registered or listed with SFDA, most significant:
    - Print/insert the registration or listing number on the product's package which imported for the local markets.
    - Writing the trade name and the storage conditions on the package in Arabic language.
    - Print production and expiration date on the packages as well as batch number.
    - Print the name and address of the manufacturer and marketing companies.
    - Translate the medication package insert into Arabic.
- Printing the two-dimensional barcode shall be observed on the packages of pharmaceutical products according to what is mentioned in Saudi Drug Code (SDC), and Drug Barcoding Specifications (DBS) that published on SFDA website.
- The packages shall be in accordance with what is mentioned in the guidelines for the pharmaceutical drug package, which published, on SFDA website.
- Free samples and educational drug products or products that are registered/listed only by SFDA are permitted.
- The phrase "**free sample**" shall be printed on the packages of the registered/listed free drugs and product with a clear writing and in Arabic. Besides, the registration/listing number shall be printed on the package and **the size of the package is not required to match the registrant.**
- The registered/listed drug and products shall be supplied **with a validity of not less than 70% of the registered validity.** As for drugs and products imported for government tenders and purchase orders, they shall be committed to supply during the period agreed upon in the supply contract and to obligate by the validity agreed upon in the contract.

- Attestation form (Attachment number 1) (**not to act until the results of the test for vaccines and blood derivatives**) **shall be attached to the Port when requesting the clearance of vaccines or human blood derivatives. As well as the form for the delivery of documents and samples for vital drugs to the laboratory** and published on the website of the agency. Besides, the samples shall be delivered to the Sector Laboratory within the specified period (48 hours) and the requirements described in "Requirements to Be Submitted for Samples of Vaccines for Test" Code shall be attached with the samples.
- A certificate shall be attached to prove that the product is free from HIV virus and hepatitis of type (D, C, B, A), certified by the Quality Manager in the factory, when requesting a clearance for drugs, biological products or medicinal products derived from human plasma.
- A certificate shall be attached to prove that the product is free from any viruses or infection when requesting a clearance for drugs, biological products or medicinal products derived from animal plasma.
- The phrase "**only for veterinary use**" shall be printed **on each packaged clearly in red colour** for each veterinary product.
- The clearance request for unregistered drugs and herbal, health or veterinary products shall be submitted electronically via IBRCS clearance system based on the import permission issued by the sector.
- The supply of unregistered products shall be in accordance with what is approved in the import permission.
- All provisions of the Code of Transportation and Storage of Products Subject to the Supervision of the Operations Sector shall be observed through Customs Ports which published on the SFDA website.
- The information on the packaging of unregistered products shall be in **English or Arabic**.
- Samples of **unregistered drugs** are **not allowed** to be submitted to the government tenders **if there is a registered and available alternative**.
- Samples of **unregistered drugs** are **not permitted** for the purpose of publicity or promotion.
- if the purchase invoice is issued by a company other than the manufacturer or marketer registered with the authority, a prior approval must be obtained from the authority (Operations - Executive Department for Inspection Support) on that before the supply.

## 3. General Notes:

- Suppliers shall be obligated to Code Number 36244 / A, dated 11/2/1438 AH, to take advantage of the Fast Track Initiative to clear registered drugs, health, herbal, and cosmetic products listed by SFDA.
- The suppliers must be obligated to code number 36244 / A, dated 11/2/1438 which stated to keep the clearance original copies for 5 years
- Samples will be drawn for analysis from the first shipment to Saudi Arabia of registered/listed drug and cleared after submitting a form (**Attestation Not to Dispose of cleared products which contain on vaccines, blood derivatives and first batch Products Received for the First Time After Registration until the analysis result is issued in addition to inform the SFDA if there are any intentions to dispose shipment. The samples and the required documents must be submitted within 48 hours from the date of clearance**). If another shipment arrives before the end of the previous attestation period or the approval is issued to dispose of these quantities, it will be cleared with another attestation not to dispose until the disposal of the first shipment is approved.
- Samples will be drawn for tests from vaccines or medicinal products derived from human plasma derivatives from every batch supplied to Saudi Arabia and cleared after submitting (**Attestation Not to Dispose of cleared products which contain on vaccines, blood derivatives and first batch Products Received for the First Time After Registration until the analysis result is issued in addition to inform the SFDA if there are any intentions to dispose shipment. The samples and the required documents must be submitted within 48 hours from the date of clearance**).
- Registered products [BULK] imported for the purpose of packaging in local factories of vaccines or blood derivatives, upon requesting their clearance, a form (**Attestation Not to Dispose of cleared products which contain on vaccines, blood derivatives and first batch Products Received for the First Time After Registration until the analysis result is issued in addition to inform the SFDA if there are any intentions to dispose shipment. The samples and the required documents must be submitted within 48 hours from the date of clearance.**
- After taking the samples in a special sealed bag and adding the sample number in the laboratories system by the Authority's inspector at the port, supplier must deliver the analysis samples of vaccines, blood derivatives, drugs and pharmaceutical products which

imported for the first time to the SFDA laboratory in Riyadh within 48 hours along with their required documents.

- Any drug or product that SFDA issued a suspension or cancelling decision against it or against its manufacturer will not be clear even if it bears prior approval for import.
- Drugs and products shall be supplied directly from its factories, noting that SFDA does not allow the import of drugs and products from free zones.
- The agent of drugs that fall within the classification of vaccines and medicinal product derived from human plasma can submit (**A Comprehensive Attestation Not to dispose the products Until the Results of the Test for All Shipments of Vaccines and Medicinal Product Derived from Human Plasma issued**) to the headquarters of Clearance and Ports Support Department in Riyadh. Thus, the attestation can be dispensed when every shipment reaches the Port of Arrival.
- The supplier shall consider when supplying vaccines or blood products to government agencies the additional samples to be submitted for analysis that exceeds the quantity required by the beneficiary.
- The manufacturer shall comply with the entry of manufactured batches into the IBRCS system for registered drugs and products.
- The products that has not been cleared due to notes or requirements that might affect their safety will not be re-imported to the Kingdom.

# 4.Requirements:

## 4.1 Clearance requirements of registered drugs and their samples to the local market.

- **The required documents to submit the clearance request:**
    1. A copy of the online clearance application form issued by the IBRCS clearance system or the clearance application number.
    2. The original manufacturer or marketer invoice, certified by the Chamber of Commerce in the country of origin or the country which issued the invoice, including the following data:
        - Invoice number and date.
        - Products Trade name.
        - Concentration and pharmaceutical form.
        - Batch number, production and expiry date.
        - Public price in Saudi Riyals and registration number.
        - Quantity, its unit and package size.
        - Manufacturer name, nationality and address.
        - Beneficiary name.
    3. A copy of bill of lading.
    4. A certificate of analysis (COA) for each batch issued and certified by the Quality Manager in the factory.
    5. Attaching the above-mentioned requirements with the application that will be submitted to SFDA through the clearance (Tbadl) platform to proceed the clearance procedures.
- **Conditions and general observations contained herein shall be reviewed and complied with.**

**4.2 Clearance requirements of registered drugs to government agencies.**

- **The required documents to submit the clearance request:**
    1. A copy of the online clearance application form issued by the IBRCS clearance system or the clearance application number.
    2. The original manufacturer or marketer invoice, certified by the Chamber of Commerce in the country of origin or the country which issued the invoice, including the following data:
        - Invoice number and date.
        - Products trade name.
        - Concentration and pharmaceutical form.
        - batch number, production and expiry date.
        - Quantity, its unit and package size.
        - Manufacturer name, nationality and address.
        - Beneficiary name.
3. A copy of bill of lading.
4. A certificate of analysis (COA) for each batch issued and certified by the Quality Manager in the factory.
5. The original copy of the approval, award, or a letter addressed to SFDA[1]
6. Attaching the above-mentioned requirements with the application that will be submitted to SFDA through the clearance (Tbadl) platform to proceed the clearance procedures

- **Conditions and general observations contained herein shall be reviewed and complied with.**
- **If the package size of the imported product is different from what is being registered in the authority, it can be cleared according to above-mentioned requirements.**

[1] [1] Submission of the original approval or awarding process can be dispensed by submitting a census request for the quantities that been awarded through email sa.gov.sfda@cps , by filling out the file designated for that (as stated in No. 3.4 of the conditions and requirements for clearance).

**4.3 Clearance requirements of registered health or herbal products and their samples**

- **The required documents to submit the clearance request:**
    1. A copy of the online clearance application issued by the IBRCS clearance system or the clearance application number.
    2. The original manufacturer or marketer invoice, certified by the Chamber of Commerce in the country of origin or the country which issued the invoice, including the following data:
        - Invoice number and date.
        - Trade name of products.
        - Concentration and pharmaceutical form.
        - Batch number, production and expiry date.
        - Products registration number.
        - Quantity, its unit and package size.
        - Manufacturer name, nationality and address.
        - Beneficiary name.
        - The public price in Saudi riyals for the products that priced by Drug Sector at SFDA.
    3. A copy of the valid registration certificate for the products to be cleared.
    4. A copy of bill of lading.
    5. A certificate of analysis (COA) for each batch issued and certified by the Quality Manager in the factory.
    6. Attaching the above-mentioned requirements with the application that will be submitted to SFDA through the clearance (Tbadl) platform to proceed the clearance procedures.

- **Conditions and general observations contained herein shall be reviewed and complied with.**

**4.4 Clearance requirements of previously listed health products that has a valid registration license.**

- **The required documents to submit the clearance request:**

1. The original manufacturer or marketer invoice, certified by the Chamber of Commerce in the country of origin or the country of export, explaining the following:
    - Invoice number and date.
    - Trade name of product and its pharmaceutical form.
    - Lot number, production and expiry date.
    - Quantity, measurement unit and package size.
    - Manufacturer name, nationality and address.
    - Products registration number.
2. A certificate of analysis for each batch issued certified by the Quality Manager in the factory.
3. A valid copy of the listing certificate for the product issued by the sector.
4. A copy of bill of lading.
5. Attaching the above-mentioned requirements with the application that will be submitted to SFDA through the clearance (Tbadl) platform to proceed the clearance procedures.

- **Conditions and general observations contained herein shall be reviewed and complied with.**

**4.5 Clearance requirements and conditions of unregistered products and drugs.**

- **Conditions:**
  - A valid import permission
- **The required documents to submit the clearance request:**

1. A copy of the valid import permit if it is not issued through IBRCS system.
2. A copy of the online clearance application form issued by the IBRCS clearance system or the clearance application number.
3. The original manufacturer or marketer invoice, certified by the Chamber of Commerce in the country of origin or the country which issued the invoice, including the following data:
   - Invoice number and date.
   - Trade name of products.
   - Concentration and pharmaceutical form.
   - Batch number, production and expiry date.
   - Quantity, its unit and package size.
   - Manufacturer name, nationality and address.
   - Beneficiary name.
4. A copy of bill of lading.
5. A certificate of analysis (COA) for each batch issued and certified by the Quality Manager in the factory
6. Attaching the above-mentioned requirements with the application that will be submitted to SFDA through the clearance (Tbadl) platform to proceed the clearance procedures.

- **Conditions and general observations contained herein shall be reviewed and complied with.**

**4.6 Clearance requirements and conditions of compassionate drug use.**

- **Conditions:**
  - Valid import permit.
- **The required documents to submit the clearance request:**
  1. A copy of the online clearance application form issued by the IBRCS clearance system or the clearance application number if sponsors or pharmaceutical companies imported the products. On the other hand, the clearance application of materials can be submitted to SFDA through clearance platform (Tbadl) attached with the followings:
  2. A copy of the valid import permit if it is not issued by IBRCS system.
  3. A copy of manufacturer or marketer invoice, certified by the Chamber of Commerce in the origin country or the country which issued the invoice, including the following data:
     - Invoice number and date.
     - Trade name of drugs.
     - Concentration and pharmaceutical form.
     - Batch number, pr
     - oduction and expiry date.
     - Quantity, measurement unit and package size.
     - Manufacturer name, nationality and address.
     - The name of the agency implementing the compassionate use program or the purpose of its clearance.
  4. A copy of bill of lading.
  5. Attaching the above-mentioned requirements with the application that will be submitted to SFDA through the clearance (Tbadl) platform to proceed the clearance procedures.
- **Conditions and general observations contained herein shall be reviewed and complied with.**
- **Conditions for obtaining an import permit shall be reviewed.**

**4.7 Clearance requirements and conditions of products and supplies for clinical studies.**

- **Conditions:**

1. Adhere to SFDA requirements for the label and packaging of drugs samples used in clinical studies as described in Circular No. 26653 / A, dated 12/12/1432 AH which published on SFDA website.
2. A valid import permission.

- **The required documents to submit the clearance request:**

1. A copy of the online clearance application form issued by the IBRCS clearance system, or the clearance application number if sponsors or pharmaceutical companies imported the products. for other products it can be submitted through the clearance (Tbadl) platform attached with the following requirements:
2. A copy of the valid import permit if it is not issued through IBRCS system.
3. The original manufacturer or marketer invoice, certified by the Chamber of Commerce in the origin country or the country which issued the invoice, including the following data:
    - Invoice number and date.
    - Trade name of products.
    - Concentration and pharmaceutical form.
    - Batch number, production and expiry date.
    - Quantity, its unit and package size.
    - Manufacturer name, nationality and address.
    - The name of the agency implementing the study or the purpose of its clearance.
4. A certificate of analysis (COA) for each batch issued and certified by the quality manager in the factory.
5. A copy of bill of lading.
6. Attaching the above-mentioned requirements with the application that will be submitted to SFDA through the clearance (Tbadl) platform to proceed the clearance procedures.

- **Conditions and general observations contained herein shall be reviewed and complied with.**
  **Conditions for obtaining an import permit shall be reviewed.**

**4.8 Clearance requirements of registered veterinary products.**

- **The required documents to submit the clearance request:**
    1. A copy of the online clearance application form issued by the IBRCS clearance system or the clearance application number.
    2. The original manufacturer or marketer invoice, certified by the Chamber of Commerce in the origin country or the country which issued the invoice, including the following data:
        - Invoice number and date.
        - Trade name of products, concentration and pharmaceutical form.
        - Batch number, production and expiry date.
        - Quantity, its unit and package size.
        - Manufacturer name, nationality and address.
        - Registration or listing number.
    3. A copy of the valid listing certificate for the listed products
    4. A copy of bill of lading.
    5. A certificate of analysis (COA) for each batch issued and certified by the Quality Manager in the factory
    6. Attaching the above-mentioned requirements with the application that will be submitted to SFDA through the clearance (Tbadl) platform to proceed the clearance procedures.
- **Conditions and general observations contained herein shall be reviewed and complied with.**

**4.9 Clearance requirements and conditions of unregistered veterinary products.**

- **Conditions:**
  - Valid import permit
- **The required documents to submit the clearance request:**
  1. A copy of the online clearance application form issued by the IBRCS clearance system or the clearance application number.
  2. A copy of a valid import permit if it was not issued by the IBRCS system.
  3. The original manufacturer or marketer invoice, certified by the Chamber of Commerce in the origin country or the country which issued the invoice, including the following data:
     - Invoice number and date.
     - Trade name of products.
     - Concentration and pharmaceutical form.
     - Lot number, production and expiry date.
     - Quantity, its unit and package size.
     - Manufacturer name, nationality and address.
  4. A copy of bill of lading.
  5. A certificate of analysis (COA) for each batch issued and certified by the Quality Manager in the factory.
  6. Attaching the above-mentioned requirements with the application that will be submitted to SFDA through the clearance (Tbadl) platform to proceed the clearance procedures.
- **Conditions and general observations contained herein shall be reviewed and complied with.**
- **Conditions for obtaining an import permit shall be reviewed.**

**4.10 Clearance requirements of samples and standard materials.**

- **The required documents to submit the clearance request:**
  1. A letter from the agent or scientific office of the manufacturing company or the local factory addressed to the sector office at the Port of Arrival requesting a clearance, stating the following:
     - Name of the product or standard substance, quantity, unit of the quantity and package size.
     - Manufacturer name, nationality and address.
     - Port of Arrival
     - The beneficiary or the purpose of the request to clear samples /standard materials.
     - Pledge to use the products only for the purpose for which they are imported.
  2. A copy of the manufacturer or marketer's invoice containing the signature and seal of the company, stating the following:
     - The name of the product or substance to be cleared, the quantity, its unit and the size of the package.
     - Manufacturer name, nationality and address.
     - Invoice number and date.
     - Beneficiary or the purpose of its clearance.
  3. A copy of the letter issued by the sector or the requesting party containing the request for samples or standard materials to be cleared, or any document proving that.[2]
  4. A copy of bill of lading.
  5. Attaching the above-mentioned requirements with the application that will be submitted to SFDA through the clearance (Tbadl) platform to proceed the clearance procedures.

- **Conditions and general observations contained herein shall be reviewed and complied with.**

[2] [2] If the application is in favour of a factory licensed by SFDA, submitting a copy of the factory license is sufficient.

**4.11 Clearance requirements and conditions of products that will be used for educational purposes.**

- **Conditions:**
  - The package of products which are intended to be used for educational purposes shall contains the following phrases:

**Important**:

- For Demonstration only.
- Not to be injected. (In case injectable product)
- Not for treatment.
- Does not contain drug product.
- Only to be used under direct supervision by medical personnel

- **The required documents to submit the clearance request:**
  1. A letter from the agent or scientific office of the manufacturing company or the local factory addressed to the sector office at the Port of Arrival requesting a clearance, stating the following:
     - Invoice number and date, trade name of the products, the quantity and its unit.
     - Beneficiary or the purpose of its clearance, besides the pledge to use the products for the purpose for which they are imported.
  2. The original manufacturer or marketer invoice, certified by the Chamber of Commerce in the origin country or the country which issued the invoice, including the following data:
     - Invoice number and date.
     - Trade name of products.
     - Batch number, quantity, measurement unit and package size.
     - Manufacturer name, nationality and address.
     - The purpose of using.
  3. A copy of bill of lading.
  4. Attaching the above-mentioned requirements with the application that will be submitted to SFDA through the clearance (Tbadl) platform to proceed the clearance procedures.

- **Conditions and general observations contained herein shall be reviewed and complied with.**

### 4.12 Clearance requirements and conditions of registered products [BULK] and imported products for the purpose of packaging in a local factory.

- **Conditions:**

1. Approval by SFDA to transfer the packaging.
2. The label of the incoming product packages, that received for the purpose of packaging, shall contains the following information in Arabic or English:
   - Product name, its concentration and pharmaceutical form.
   - Batch number, production and expiry date.
   - Manufacturer name and nationality.
   - Package size and weight.
   - Manufacturer recommended storage degree.

- **The required documents to submit the clearance request:**

1. A copy of the online clearance application form issued by the IBRCS clearance system or the clearance application number.
2. The original manufacturer or marketer invoice, certified by the Chamber of Commerce in the origin country or the country which issued the invoice, including the following data:
   - Invoice number and date.
   - Trade name of products.
   - Concentration and pharmaceutical form.
   - Lot number, production and expiry date.
   - Quantity, measurement unit and package size.
   - Manufacturer name, nationality and address.
3. A copy of the approval letter for packaging issued by the sector (attached to the application which will be submitted through IBRCS.
4. A copy of bill of lading.
5. Attaching the above-mentioned requirements with the application that will be submitted to SFDA through the clearance (Tbadl) platform to proceed the clearance procedures.

- **Conditions and general observations contained herein shall be reviewed and complied with.**

**4.13 Clearance requirements and conditions of empty bottles for pharmaceutical packaging.**

- **Conditions:**

1. It is not allowed to issue a clearance for packages that contain trademarks/names do not belong to the importer, without the approval of the manufacturer (the beneficiary).
2. If the packages are imported through a warehouse licensed by SFDA, certified attestation from the Chamber of Commerce stating that it will be sold only for the factories or bodies that are licensed by SFDA.
3. If the packages are imported through an unlicensed warehouse from the sector, or if these packages contain the names of the products, a letter addressed to the sector office at the arrival port by the licensed facility (factory) requesting to submit these packages.

- **The required documents to submit the clearance request:**

1. A letter from the supplier addressed to the Sector Office at the Arrival Port, requesting approval to clear the empty packages, including the following:
   - The purpose of importing the empty packages and pledging to use them for that purpose.
   - Names of products, their quantities, and the manufacturer.
2. The original purchase invoice certified by the Chamber of Commerce in the origin country or the country which issued the invoices.
3. A copy of the valid certificate of the factory or warehouse license issued by SFDA.
4. A certificate from the source proving that the product is free from pork derivatives and its safety from Transmissible TSEs (Encephalopathies Spongiform) if the product that inten ded to be cleared are Gelatine capsules from an animal source.
5. A copy of bill of lading.
6. Attaching the above-mentioned requirements with the application that will be submitted to SFDA through the clearance (Tbadl) platform to proceed the clearance procedures.

- **Conditions and general observations contained herein shall be reviewed and complied with.**

**4.14 Clearance requirements of primary chemical martials [. A.P. I] for local factories that licensed by SFDA.**

- **The required documents to submit the clearance request:**

1. The original certified purchase invoice including all the data for the materials required to be cleared as follows:
   - Scientific name of the primary chemical.
   - Quantity and unit.
   - The name and address of the manufacturer.
   - Batch number.
2. A copy of the licence of the manufacturer or warehouse which issued by SFDA.
3. A copy of bill of lading.
4. Attaching the above-mentioned requirements with the application that will be submitted to SFDA through the clearance (Tbadl) platform to proceed the clearance procedures.

- **Conditions and general observations contained herein shall be reviewed and complied with.**

## 4.15 Clearance requirements and conditions for obtaining chemicals.

**Important note:**

- Operations Sector is responsible for importing and clearing chemicals that are used for health purposes or included in the composition of products that are only subject to the SFDA supervision.
- The clearance of chemical materials for pharmaceutical /cosmetic factories, pharmacies and laboratories will be issued by SFDA and health sectors.
- The import and clearance of chemical precursors stated in the executive regulations of the chemical substances import law from the second and third list will be through the Narcotic Drugs Administration at the Drug Sector headquarters in Riyadh.
- The below mentioned forms (No. 1, 2, 8 and 10) can be obtained from the executive regulations of the Chemicals Import Law, published on SFDA website (the Laws and Regulations page).

**First: Clearance of dangerous chemicals that are used in the composition of explosives (first list)**

- **Procedures for obtaining clearance permission:**

1. The importer who has obtained permission to import chemicals shall apply to the Ministry of Interior (MOI) (the General Secretariat of the High Commission for Industrial Security - Central Security Licensing Unit) with a request letter to obtain clearance permission for each imported shipment, not less than ten working days prior to the shipment's actual arrival date.
2. The Ministry of Interior (the General Secretariat of the High Commission for Industrial Security - Central Security Licenses Unit) completes the procedures for requesting a clearance permit. Besides issuing and approving the clearance, and sends the original clearance permission to the customs.

- **Documents required to be submitted to Industrial Security to obtain a clearance permit:**
  **A request letter to obtain clearance permission for the chemical materials addressed to the Ministry of Interior (the General Secretariat of the High Commission for Industrial Security - Central Security Licensing Unit), accompanied by the following:**
    1. Application form for permission to clear chemicals, Form No. (10) after completing it.

2. A copy of a valid import permit iisued from the Industrial Security.
3. A clear copy of the purchase invoice including the invoice number, date, name in addition to the address of the manufacturer and exporter. Besides, scientific and commercial name of the chemicals and their quantity must be written in a clear legible in both Arabic and English.
   A clear copy of origin certificate signed, sealed and certified by the concerned authority in the country of origin.
4. A clear copy of the Imported material safety data sheet (MSDS) in English stamped with the importer's seal and translated into Arabic by an accredited translation office.

**Note: If the application approved, SFDA will contact the Industrial Security at the Ministry of Interior to recommend the issuance of import and clearance license.**

**Second: Clearance of unrestricted or forbidden chemicals (List Nine)**

- **Procedures required to be submitted in order to obtain a release permit:**

1. The importer who has obtained permission to import chemicals shall apply to the Operations Sector office at the port of arrival with a request letter to obtain clearance permission for each imported shipment not less than ten working days prior to the actual arrival date of the shipment.

- **Documents required to be submitted to Industrial Security to obtain a clearance permit:**

  **A letter containing a request to obtain permission to clear chemical materials directed to the pharmaceutical sector at SFDA, accompanied by the following:**

  1. Application form for permission to clear chemicals, Form No. (10) after completing it.
  2. A copy of a valid import permit.
  3. A clear copy of the purchase invoice including the invoice number, date, name in addition to the address of the manufacturer and exporter. Besides, scientific and commercial name of the chemicals and their quantity in clear legible handwriting in both Arabic and English.
  4. A clear copy of origin certificate signed, sealed and certified by the concerned authority in the country of origin.
  5. A clear copy of the Imported material safety data sheet (MSDS) in English stamped with the importer's seal and translated into Arabic from an accredited translation office.
  6. Attaching the above-mentioned requirements with the application that will be submitted to SFDA through the clearance (Tbadl) platform to proceed the clearance procedures

- **Conditions and general observations contained herein shall be reviewed and complied with.**

**4.16 Conditions and requirements for the clearance of raw medicinal plants.**

- **Conditions:**

1. Relocation packages shall have external stickers in English or Arabic containing the following information:
   (Scientific name, common name, country of cultivation and collection, date of harvest, date of collection and part used).
2. If there is a technical note on the plant to be cleared, if there is a suspicion that the means of preservation or transportation are not good, or if the analysis certificates are not attached, thus samples will be taken by the pharmaceutical sector inspectors at the arrival port and sent for analysis in the laboratories of the pharmaceutical sector. The shipment will be cleared according to supplier attestation (certified by the Chamber of Commerce) that contains all the data on the shipment not to dispose of until the results of the analysis appear and the authority's approval to dispose of the shipment is published on SFDA website (a pledge not to dispose of plants until the results of the analysis issued).

- **The required documents to submit the clearance request:**

1. The original invoice of the company, certified by the Chamber of Commerce and contains the following data:
   - Invoice number
   - Quantity, measurement
   - Scientific name of the plant to be cleared
2. A phytosanitary certificate from the country of export containing the following data:
   - Scientific name of the plant
   - Common name of the plant
   - Origin country
   - The purpose of final use
   - The quantity is in kilogram
   - Transportation method
   - Preservation method (wet or dry)

3. An original certified certificate of analysis issued by the country of origin that includes the following:
    - The result of microbiological analysis (bacteria, fungi and pathogenic bacteria)
    - The result of analysing toxic elements (lead, arsenic, cadmium and mercury)
4. A copy of the commercial register stating that the importer is allowed to practice importing these plants.
5. A copy of bill of lading.
6. **Attaching the above-mentioned requirements with the application that will be submitted to SFDA through the clearance (Tbadl) platform to proceed the clearance procedures.**

- **Conditions and general observations contained herein shall be reviewed and complied with.**