



Regulation and Requirements for Import, Clearance and Export

Version 1.0

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[Regulations and Requirements for Import, Clearance and Export]

Version 1.0

Drug Sector
Saudi Food & Drug Authority
Kingdom of Saudi Arabia

*Please visit SFDA's website at <http://www.sfda.gov.sa> for the
latest update*

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I. Import

1. Regulations and Requirements for Importing Unregistered Medications, Health and Herbal Products

First: import requests for governmental and private hospitals.

- **Regulations:**

1. The imported product must be important and do not have registered alternative in the Kingdom.
2. The manufacturer should be registered at SFDA unless the product could not be obtained from the registered manufacturer.
3. The product must be marketed in the country of origin.
4. The required quantity must be sufficient for six months maximum.
5. Such product shall not be sold or loaned to any other party, without drug sector permission.

- **The required documents for import license:**

- ❖ If the beneficiary did not take a prior approval from the SFDA to import the required product, an application form of the unregistered product must be filled; the Form is available at the SFDA website (Attached Below) and submitting the required documents below.
- ❖ If the beneficiary had obtained an approval for importing the required product, submitting a letter to the drug sector, including on a request for approval to import the required products along with their data as per the following:

Trade Name	Generic Name	Concentration	dosage Form	Package Size	Quantity	Unit
-	-	-	-	-	-	-

- Name and nationality of the manufacturer.
- Name and nationality of the marketing company.
- Importer name.
- Justification of importing mentioning the therapeutic advantage that differs from other registered therapeutic alternatives.

- In case of requesting an import license for an unregistered product that has registered alternative, justifications of not obtaining the registered alternative shall be stated.
- In case of requesting an import license from an unregistered companies, the justifications of not importing from registered companies shall be stated.
- The following phrase shall be written in the letter:

Importing these products will be under our responsibility and will only be used for the hospital patients; and we pledge in case of quantity increasing or decreasing, or terminating the award with the supplier, we will notify the SFDA and will not give it to any other agency without SFDA approval, and in case of refusing the acceptance of the products for any technical reason or for not matching the specifications and terms of importing, we will detain the quantity and notify the Authority.

- **A certification that proves the registration and marketing of the product in the country of origin shall be submitted with the request.**

- **Importing application process:**

- **Submitting the application directly by the beneficiary:**

1. Submit the original letter to the drug sector headquarters in Riyadh.
2. The import request will be processed, and the importer will be informed to submit for import license through IBRCS system in case of approval, and in case of rejection, the beneficiary will be informed.

- **Submitting the application by the importer:**

1. The importer shall apply for an import license through IBRCS system on the bases of the letter of the beneficiary and attach the beneficiary letter.
2. If the beneficiary has given the original letter to the importer, the original letter should be submitted to the drug sector headquarters after issuing the final decision regarding the import license.
 - ❖ If beneficiaries want to send the import request letters by E-mail, an official letter addressed to the drug sector shall be sent to acquire the

authorization for the E-mail addresses that will be sending the letters.

When the sector approves the E-mail, all importing request letters should be sent by e-mail, while the original letters should be kept with the beneficiary and not been sent nor will be given to the importer.

- In case of cancelling or modifying an e-mail, the drug sector must be notified by an official letter.

Second: Unregistered products importing applications of Gulf (SGH) tender or National Unified Procurement Company (NUPCO) tender only:

- **Importing application process:**

1. The importer shall apply for an import license request through IBRCS system based on the award sheet and attach a copy of the award in the system.
 2. The original award of the tender shall be submitted to the drug sector headquarters in Riyadh after issuing the final decision regarding the application for matching the information.
- ✓ All original award sheets will be returned after being checked and marked indicating the issuing of importing license.

**APPLICATION FOR PERMISSION
TO IMPORT AN UNREGISTERED MEDICINAL PRODUCT**

SECTION A - PRODUCT DETAILS

Product Name (including dosage form & strength):	Quantity Applied:
Name & Strength of Active Ingredient(s):	Pack Size:
	Route of Administration:
Name & Address of Manufacturer:	

SECTION B – JUSTIFICATIONS

Purpose <i>(Tick appropriate box)</i>	<input type="checkbox"/> for Named-Patient <input type="checkbox"/> as Buffer Stock
Dosage Regimen	
Claim / Indication	
Products that have been used before for treatment	
Reason(s) for not using registered product(s)	
Declaration	<p>Name of Hospital/Clinic:</p> <p>Address of Hospital/Clinic:</p> <p><u>Declaration :</u></p> <p>1. I am fully aware that the above medicinal product has not been evaluated for the required quality, safety and efficacy standards for supply in Saudi Arabia. The importation is requested for the purpose of administering the medicinal product to a patient under my care and I undertake to assume full responsibility for its use on the patient under my care.</p> <p>2. I undertake to maintain records of the name, identification document number and contact details of the patient who received the above medicinal product under my care.</p> <p>Signature:</p> <p>Date:</p>

2. The Process of Importing Registered Pharmaceutical Products That Will Be Supplied on Batches for the Governmental Tenders

- ❖ The pharmaceutical products which are registered by SFDA drug sector and imported for the benefit of the Governmental tenders and will not have a registration number or public price there quantity will be limited without having an import license as per the following:
 - The imported registered pharmaceutical products must be identical to what registered at SFDA in concentration, pharmaceutical form, name and nationality of the Manufacturer.
- **The applying process for quantity Limitation:**

Applying for the schedules of quantity Limitation for the tenders shall be conducted by the products agent who is awarded the tender, by e-mail:

Clearance.Drug@sfda.gov.sa

The agent should mention all awarded products that are registered at SFDA in the schedule with the following information:

- a) Tender Name: e.g. (Gulf (SGH) Tender, NUPCO Tender, and Ministry of Defense Tender, etc.)
- b) Tender Number: e.g. (35, 45, and 0011/2012, etc.)
- c) Agent Name: the Agent who will import the product(s) for the tender.
- d) Date of Import: according to what is shown in the tender.
- e) The date when the import agreement will be ended: according to what is shown in the tender.
- f) Item No.: e.g. (123/a, 00122011100001.)

- g) Name and Nationality of the Manufacturer.
- h) Trade Name.
- i) Total Awarded Quantity,
- j) Unit: (tablet, vial, capsules, and bottle, etc.) or to be by a pack (pack/ 30 tablet, or pack/ 6 ampoules.)
- **The schedule shall be resent after being filled to the e-mail and attach a copy of the tender contract or the award letter.**
- ❖ **The registered pharmaceutical products that imported for a governmental party arriving as one shipment do not require the above-mentioned process. Moreover, drug sector office at the port of arrival shall be provided with the original award or the contract for matching, deducting the quantity, and returning them to the importer.**

II. Clearance

1. Regulations and Requirements for Clearance of Un-Registered Pharmaceutical Products

Unregistered Pharmaceutical products: are those which registration process at the SFDA has not been completed and will be imported according to the requirements and regulations due to their importance and need by health agencies.

- **Regulations:**

- 1- Import of such products should be done in accordance with what is mentioned in the import License.
- 2- Full compliance with transport and storage conditions which are published at SFDA website.
- 3- A Data logger should be placed to register the temperature of the shipment according to what is mentioned in the related guideline and approved Data logger specifications, **Also, the serial number of the Data logger should be written in one of the shipment documents.**
- 4- When requesting a clearance of vaccines and blood products, a signed written pledge (obligation) must be provided stating that such products will not be used, and samples will be submitted to SFDA Laboratories within the specified period. The pledge (obligation) form is available at the authority's website.
- 5- When requesting a clearance of biological and blood products, a certificate of analysis signed by the quality manager at the manufactory, should be submitted stating that the products are free from HIV and hepatitis (A, B, C, & D) viruses.
- 6- A valid import License issued by the SFDA must be available.
- 7- Submit the clearance application by (IBRCS) clearance system.
- 8- Submit all required documents to the Drug Sector Office at the port of arrival.

- **Documents to be Submitted for Clearance:**

- 1- A copy of the clearance application from (IBRCS) clearance system or the application number.
- 2- The original invoice of the manufacturer or the marketing company certified by the chamber of commerce at the country of origin or the issuing country.

The invoice should include the following information:

- a) The invoice number and date.
 - b) The trade names of the products.
 - c) Concentration and pharmaceutical form.
 - d) Batch number, production date and expiration date.
 - e) Quantity, unit and package size.
 - f) Name, nationality and address of the manufacturer.
 - g) Name of the beneficiary.
- 3- The certificate of origin (original copy) certified by the chamber of commerce at the country of origin or the exporting country.
- The certificate should state the beneficiary name, batch number, quantity, manufacturer's name and its nationality or otherwise, the number and date of the invoice.
- 4- A copy of the import License.
 - 5- A copy of the bill of lading.
 - 6- A copy of the warehouse and manager's license.
 - 7- A certificate of analysis for each batch issued and certified by the quality manager at the manufactory.
 - 8- A copy of the custom statement.

2. Regulations & Requirements of Registered Medications clearance for the Local Market

Registered Medications: are those Medications of which their registration process at the SFDA or the Ministry of Health has been completed and accordingly were issued a registration number and certificate.

Regulations:

- 1- Importing medications must be in accordance with the registered standards of which the most important are:
 - a) Printing the registration number, agent's name and the public price in Saudi Riyals on the package.
 - b) Writing the trade name, storage conditions in Arabic language on the package.
 - c) Translation of the inner leaflet to Arabic.
 - d) Printing the production date, expiry date and batch No. on the package.
- 2- Imported products should have at least 70% remaining of their shelf life.
- 3- Full compliance with transport and storage conditions which are published at SFDA website.
- 4- A Data logger should be placed to register the temperature of the shipment according to what mentioned in the related guideline and approved Data logger specifications. **Also, the serial number of the Data logger should be written in one of the shipment documents.**
- 5- If the registered products are imported to Saudi Arabia for the first time, samples will be taken from the shipment and the agent will sign a written pledge (obligation) stating that such products will not be used until the results of sample analysis is issued from the SFDA Laboratories. The pledge (obligation) form is available at the SFDA website.
- 6- When requesting a clearance of vaccines and blood products, a signed written pledge (obligation) must be provided stating that such products will not be used, and samples will be submitted to SFDA Laboratories within the

specified period. The pledge (obligation) form is available at the authority's website.

- 7- When requesting a clearance of biological and blood products, a certificate of analysis signed by the quality manager at the manufactory, should be submitted stating that the products are free from HIV and hepatitis (A, B, C, & D) viruses.
- 8- Samples of registered medication must have the registration number and agent name and the phrase (FREE SAMPLE) on the outer pack written in Arabic language.
- 9- Submit the clearance application by (IBRCS) clearance system.
- 10- Submit all required documents to the Drug Sector Office at the port of arrival.

- **Documents to be Submitted for Clearance:**

- 1- A copy of the clearance application from (IBRCS) clearance system or the application number.
- 2- The original invoice of the manufacturer or the marketing company certified by the chamber of commerce at the country of origin or the issuing country.
The invoice should include the following information:
 - a) The invoice number and date.
 - b) Product trade name.
 - c) Concentration and pharmaceutical form.
 - d) Batch number, production date and expiration date.
 - e) Public price in Saudi riyal and registration number.
 - f) Quantity, unit and package size.
 - g) Name, nationality and address of the manufacturer.
 - h) Name of the beneficiary.
- 3- The certificate of origin (original copy) certified by the chamber of commerce at the country of origin or the exporting country.
 - The certificate should state the beneficiary name, batch number, quantity, manufacturer's name and its nationality or otherwise, the number and date of the invoice.



- 4- A valid copy of the registration certificate for the products intended to be cleared.
- 5- A copy of the bill of lading.
- 6- Valid copies of the warehouse and the warehouse manager licenses.
- 7- A certificate of analysis for each batch issued and certified by the quality manager at the manufactory.
- 8- A copy of the custom statement.

3. Regulations & Requirements of Registered Health and Herbal Products Clearance

Registered health and herbal products: the products which their registration process at the SFDA or the Ministry of Health has been completed and accordingly were issued a registration number and certificate.

- **Requirements:**

- 1- Importing products must be in accordance with the registered standards of which the most important are:
 - e) Printing the registration number, agent name and public price in Saudi Riyals (for products priced by SFDA), on the package.
 - f) Writing the trade name, storage conditions in Arabic language on the package.
 - g) Translating the inner leaflet to Arabic.
 - h) Printing the production date, expiry date and batch No. on the package.
- 2- It is important to not include any medical claim that is not approved by the SFDA.
- 3- Imported products should have at least 70% remaining of their shelf life.
- 4- Full compliance with transport and storage conditions which are published at SFDA website.
- 5- A Data logger should be placed to register the temperature of the shipment according to what mentioned in the related guideline and approved Data logger specifications. **Also, the serial number of the Data logger should be written in one of the shipment documents.**
- 6- If the registered products are imported to Saudi Arabia for the first time, samples will be taken from the shipment and the agent will sign a written pledge (obligation) stating that such products will not be used until the results of sample analysis is issued from the SFDA Laboratories. The pledge (obligation) form is available at the SFDA website.

- 7- Samples of registered health products must have the registration number and agent name and the phrase (FREE SAMPLE) on the outer pack written in Arabic language.
- 8- Submit the clearance application by (IBRCS) clearance system.
- 9- Submit all required documents to the Drug Sector Office at the port of arrival.

- **Requirements:**

- 1- A copy of the clearance application from (IBRCS) clearance system or the application number.
- 2- The original invoice of the manufacturer or the marketing company certified by the chamber of commerce at the country of origin or the issuing country.
The invoice should include the following information:
 - a) The invoice number and date.
 - b) Product trade name.
 - c) Concentration and pharmaceutical form.
 - d) Batch number, production date and expiry date.
 - e) Registration number for each product
 - f) Quantity, unit and package size.
 - g) Name, nationality and address of the manufacturer.
 - h) Name of the beneficiary.
 - i) Public Price in Saudi Riyals for products priced by SFDA.
- 3- The certificate of origin (original copy) certified by the chamber of commerce at the country of origin or the exporting country.
 - The certificate should state the beneficiary name, batch number, quantity, manufacturer's name and its nationality or otherwise, the number and date of the invoice.
- 4- A valid copy of the registration certificate for the products intended to be cleared.
- 5- A copy of the bill of lading.
- 6- A copy of the customs statement
- 7- A certificate of analysis for each batch issued and certified by the quality manager at the manufactory.
- 8- Valid copies of the warehouse and the warehouse manager licenses.

4. Regulations and Requirements for Clearance of Samples and Standard Materials

- ❖ **The samples of unregistered Medications shall not be allowed to enter to Saudi Arabia for tender if there is a registered and available alternative.**
- ❖ **The Samples of the unregistered products shall not be allowed to enter to Saudi Arabia for the purpose of advertising or promotions.**

- **Regulations:**

1. Full compliance with transport and storage conditions which are published at SFDA website.
2. A data logger should be placed to register the temperature of the shipment according to what is mentioned in the related guideline and approved Data logger specifications, **Also, the serial number of the Data logger should be written in one of the shipment documents.**
3. Submit all required documents to the Drug Sector Office at the port of arrival.

- **Requirements:**

1. A letter from the agent or the scientific office of the manufacturer to SFDA drug sector stating the following:
 - a) The name of product or the standard materials, quantity, unit and the Package size.
 - b) The name and nationality of the manufacturer.
 - c) Port of arrival

- d) The beneficiary and the purpose for requesting clearance of samples or standard materials.
 - e) A pledge to not use such products unless for its intended purpose.
- 2. A copy of the invoice of the manufacturer or the marketing company certified includes the following:
 - a) The name of products or the standard materials, quantity, unit and the Package size.
 - b) The name and nationality of the manufacturer.
 - c) The invoice number and date.
 - d) The beneficiary or the purpose of clearance.
- 3. A copy of the letter issued by SFDA or the beneficiary that include the request for the samples or the standard materials that needed to be cleared, or any document proof that request.
- 4. A copy of the bill of lading.
- 5. A copy of the custom statement.

5. Regulations & Requirements for Clearance of Products for Educational Purposes

- **Regulations:**

- 1- Only SFDA registered medicines and pharmaceuticals products are allowed to be imported for Educational Purposes.
- 2- Products which are intended to be used for educational purposes should have the following text written clearly on the their packages:

- **Important:**

- For demonstration only.
 - Not to be injected (in case of injectable products).
 - Not for treatment.
 - Does not contain drug products.
 - To be used only under direct supervision by medical personnel.
- 3- Submit all required documents to the Drug Sector Office at the port of arrival.

- **Documents to be Submitted for Clearance:**

- 1- A clearance request letter from the importer or the scientific office of the manufacturer submitted to SFDA Drug Sector office at port of arrival include the following:
 - a) The invoice number and date, Trade name of the products, registration number, quantity and its unit.
 - b) Name of the beneficiary and the purpose for clearance and a pledge from the importer to use the products only for Educational Purposes.
- 2- The original invoice of the manufacturer or the marketing company certified by the chamber of commerce at the country of origin or the issuing country.

The invoice should include the following information:

- a) The invoice number and date.
- b) Trade name of the Products.
- c) Batch number, quantity, unit and package size.
- d) Name, nationality and address of the manufacturer.

- e) Clarify that these products are for educational purposes.
- 3- The certificate of origin (original copy) certified by the chamber of commerce at the country of origin or the issuing country.
- 4- A copy of the bill of lading.
- 5- A copy of the customs statement.

6. Regulations & Requirements for Import and Clearance of Chemicals

- **Notices:**

- 1- Import and clearance of controlled chemical precursors shall be submitted to Narcotics and control Drug Department at drug sector.
- 2- If the chemicals to be imported or cleared are enlisted in the list of controlled substances by public security at the ministry of interior, they shall be submitted in a separate application along with previous requirements and the safety and security form, stamped by the importer. The clearance license together with the safety and security form shall be sent to the Public Security at the Ministry of Interior.
- 3- If the chemicals to be imported or cleared are enlisted in the tables of Prohibition of Chemical Weapons Convention, they shall be submitted in a separate application along with previous requirements. The clearance license shall be sent to the Laboratories and Quality Control Department at the Ministry of Commerce & Industry.
- 4- Import and clearance of chemicals to be used for commercial and industrial purposes shall be through the Ministry of Commerce & Industry.

Import:

- The following requirements shall be submitted to the Drugs Sector Office at the port of arrival:
 - 1- A letter from the requesting or importing party showing the following:
 - a) The scientific name and quantity of the chemical substance.
 - b) The name and address of manufacturer, exporter and importer.
 - c) Stating the beneficiary party and the purpose of use
 - 2- Attach a copy of the contract, award letter or purchase order from the beneficiary showing the requested substances and their quantities^(*).

(*) This requirement is not required if the import is intended for the local market and instead, provision No. 5 shall apply.

- 3- A copy of the warehouse license issued by the Saudi Food & Drug Authority (SFDA) or a still valid one which had been issued by the Health Affairs, Ministry of Health.
- 4- A copy of the invoice or initial invoice issued by the manufacturer.
- 5- In case import is intended for the local market, an authenticated pledge should be submitted, every six months, to provide SFDA with the supplied, used and remaining quantities as well the parties benefiting from such imported chemicals

Clearance:

- The following requirements shall be submitted to the Drugs Sector Office at the port of arrival:
 1. A letter from the importer.
 2. A copy of the warehouse license issued by the Saudi Food & Drug Authority (SFDA) or a still valid one which had been issued by the Health Affairs, Ministry of Health.
 3. A copy of the import license and the previously approved invoice.
 4. Certificate of origin certified by the chamber of commerce at the country of origin or the exporting country.
 5. An invoice certified by the chamber of commerce at the country of origin showing the following:
 - a. Invoice number and date
 - b. Name and address of the manufacturer, exporter and importer
 - c. The scientific name and quantity of the chemical substance as mentioned in the import license.

7. Regulations & Requirements for Registered Products Clearance for Government Agencies

Registered Medications: are those Medications of which their registration process at the SFDA or the Ministry of Health has been completed and accordingly were issued a registration number and certificate.

- **Regulations:**

- 1- Importing medications must be in accordance with the registered standards of which the most important are:
 - i) Writing the trade name and storage conditions in Arabic language.
 - j) Translation of the inner leaflet to Arabic.
 - k) Printing the production date, expiry date and patch No. on the package.
- 2- Full compliance with transport and storage conditions which are published at SFDA website.
- 3- A Data logger should be placed to register the temperature of the shipment according to what mentioned in the related guideline and approved Data logger specifications. **Also, the serial number of the Data logger should be written in one of the shipment documents.**
- 4- If the registered products are imported to Saudi Arabia for the first time, samples will be taken from the shipment and the agent will sign a written pledge (obligation) stating that such products will not be used until the results of sample analysis is issued from the SFDA Laboratories. The pledge (obligation) form is available at the SFDA website.
- 5- When requesting a clearance of vaccines and blood products, a signed written pledge (obligation) must be provided stating that such products will not be used, and samples will be submitted to SFDA Laboratories within the specified period. The pledge (obligation) form is available at the authority's website.

- 6- When requesting a clearance of biological and blood products, a certificate signed by the quality manager at the manufactory, should be submitted stating that the products are free from HIV and hepatitis (A, B, C, & D) viruses.
- 7- Submit the clearance application by (IBRCS) clearance system.
- 8- Submit all required documents to the Drug Sector Office at the port of arrival.

- **Documents to be Submitted for Clearance:**

- 1- A copy of the clearance application from (IBRCS) clearance system or the application number.
- 2- The original invoice of the manufacturer or the marketing company certified by the chamber of commerce at the country of origin or the issuing country.

The invoice should include the following information:

- a) The invoice number and date.
 - b) Product trade name.
 - c) Concentration and pharmaceutical form.
 - d) Batch number, production date and expiry date.
 - e) Quantity, its unit and package size.
 - f) Name, nationality and address of the manufacturer.
 - g) Name of the beneficiary.
- 3- The certificate of origin (original copy) certified by the chamber of commerce in the country of origin or the exporting country.
 - The certificate should state the beneficiary name, batch number, quantity and the manufacturer's name and its nationality or otherwise, the number and date of the invoice.
 - 4- A valid copy of the registration certificate for the products intended to be cleared.
 - 5- A copy of the bill of lading.
 - 6- A copy of the warehouse and the warehouse manager licenses.
 - 7- A certificate of analysis for each batch issued and certified by the quality manager at the manufactory.

- 8- A copy of the custom statement.
- 9- The original award, quotation or a letter from the beneficiary addressed to SFDA (*).

(*) Submission of the original award or quotation can be replaced by a request of quantity limitation of the awarded quantities through the E-mail: clearance.drug@sfda.gov.sa by filling in the relevant file.

8. Regulations and Requirements for Clearance of Empty Containers for Filling or Packaging of Medicines, Pharmaceutical or Cosmetic Products

- **Regulations:**

1. If the importer of the empty containers is an SFDA licensed warehouse, a pledge (obligation) certified by the chamber of commerce for not selling the empty containers except for the licensed manufacturer or other licensed parties must be provided.
2. If the importer of the empty containers is a warehouse not licensed by SFDA, a letter must be provided to SFDA from the SFDA licensed party that is requesting these empty containers.
3. Submit all required documents to the Drug Sector Office at the port of arrival.

- **Documents to be submitted for clearance:**

1. A letter from the agent requesting clearance approval for the empty containers including the following:
 - a) The purpose for importing these empty containers and a pledge (obligation) to use it for this purpose.
 - b) Name of products, quantities and the manufacturer.
2. The original invoice certified by the chamber of commerce at the country of origin or the exporting country.
3. The certificate of origin certified by the chamber of commerce at the country of origin or the exporting country.
4. A copy of the manufacturer registration certificate issued by SFDA, or a copy of the industrial license for cosmetic manufacturer in case of importing it for a licensed manufacturer or if the importer is not licensed by SFDA.
5. A valid copy of the importer warehouse license.
6. A certificate confirms that the imported empty containers are free from pork derivatives, if the imported empty containers are gelatin capsules.
7. A copy of the Customs statement.
8. A copy of bill of lading.

9. Regulations and Requirements for Clearance of Raw Medical Plants

- **Regulations:**

1. Containers shall have external labels, includes the following information:

Scientific name, common name, country of agriculture and harvesting, date of harvesting and the used part.

2. Quality of Raw medical plants shall be maintained during transportation process, and safety requirements shall be considered during transporting Raw medical plants, especially, which may be poisoned or harmed. In addition, the following requirements must be implemented:

- a) Containers (units) of packing shall be clear and dry.
- b) Containers (units) of packing and transportation methods (land, sea, and air) shall be suitable for transportation of the raw medical plants, taking into consideration requirements of the status of the transported plants (dry or fresh) regarding temperature, ventilation and humidity, according to the following:
 - i. Fresh plants shall be transported through transportation units that have enough and suitable ventilation, taking into consideration that they shall not be exposed to light, dust, rains and high temperature, according to the requirements of each plant.

- ii. Dry plants shall be transported through transportation units, which protect them from humidity, taking into consideration that they shall not be exposed to light, dust, rains and high temperature, according to the requirements of each plant.
 3. The supplier shall store them in accordance with storing conditions which are suitable to the status and type of each plant that mentioned in scientific principles and standards, taking into consideration expedite procedures of clearance and transportation to the warehouses.
- If there is a technical note on the plant, intended to be cleared, or if there a suspicion in the quality of stock and transportation methods, samples will be taken by Drugs Sector inspectors at the port of arrival, and sent to be analyzed at laboratories of Drug Sector. The clearance of shipment will be executed according to a pledge of the supplier, including data of shipment, and accepted by the Chamber of Commerce not to use until result of testing issued, and until acceptance of the Authority for using the shipment.
 - **Documents to be Submitted for Clearance:**
 1. A letter from the supplier to Saudi Food & Drugs Authority - Drug Sector at the port of arrival, mentioning all details of the medicinal plant which intended to be cleared, and mentioning the purpose of import.
 2. Invoice from exporting company, certified by the Chamber of Commerce, including the following information:
 - a. Number and date of the invoice.
 - b. Scientific name of the plant which intended to be cleared.

- c. Quantity and unit.
- 3. Certificate of origin, certified by the Chamber of Commerce in the country of origin or exporting country, including details of plant that intended to be cleared, or invoice number and date.
- 4. Plant health certificate from the exporting country, including the following details:
 - a) Scientific name of the plant.
 - b) Common name of the plant.
 - c) Country of origin.
 - d) Uses of the final product.
 - e) Quantity in kilograms.
 - f) Mean and method of transportation.
 - g) Storing conditions (dried or wet).
- 5. Certificate of analysis from the country of origin, including the following:
 - a) Result of the microbiological analysis (Bacteria, Fungus and Pathogens).
 - b) The result of the toxic elements analysis (Lead, Arsenic, Cadmium, and Mercury).
- 6. A copy of the commercial registration, clarifying the permission to perform such practice by the importer.
- 7. A copy of bill of lading.
- 8. A copy of Customs statement.

10. Regulations and Requirements for Registered Product (Bulk) Clearance For The Purpose of Secondary Packaging at Local Manufacturer

- **Regulations:**

1. The approval of SFDA drug sector on the secondary packaging or it must be stated in the Registration Certificate.
2. Full compliance with transport and storage conditions which are published at SFDA website.
3. A Data logger should be placed to register the temperature of the shipment according to what is mentioned in the related guideline and approved Data logger specifications. **Also, the serial number of the Data logger should be written in one of the shipment documents.**
4. If the registered products are imported to Saudi Arabia for the first time, the agent must submit a pledge (obligation) certified from the Chamber of Commerce stating that these products will not be marketed until it been analyzed by SFDA laboratories and get the approval from the SFDA for the product.
5. A pledge (obligation) for not using the imported products must be provided upon requesting the clearance for vaccines and blood products until it been analyzed after the secondary packaging and commit to deliver the samples to SFDA Drug Sector Laboratories after finishing the secondary packaging in accordance to the pledge form available at SFDA website and the samples must be delivered to SFDA Laboratories within the specified period.

6. When requesting the clearance of biological and blood products, a certificate signed by the quality manager at the Manufacture, should be submitted stating that the products are free from HIV and hepatitis (A, B, C, & D) viruses.
7. Submit all required documents to the Drug Sector Office at the port of arrival.
8. The package label of the secondary packaging product must contain the following information:
 - a) The Product Name, concentration, and pharmaceutical form.
 - b) Batch number, production date and expiry date.
 - c) Name and nationality of the manufacturer.
 - d) The package size or the package weight.
 - e) The manufacturer recommended storage temperature.

- **Documents to be submitted for clearance:**

1. A letter from the agent requesting clearance approval for the products including the following:
 - a) The invoice number and port of arrival.
 - b) Trade name, concentration and Pharmaceutical form, batch number, quantity and name and nationality of the manufacturer.
 - c) The beneficiary and the purpose for importing the product.
 - d) A pledge from the agent to use the products for its imported purpose.
2. The invoice of the manufacturer or the marketing company certified by the chamber of commerce at the country of origin or the issuing country include the following information:

- a) The invoice number and date.
 - b) Product trade name.
 - c) Concentration and Pharmaceutical form.
 - d) Batch number, production date and expiry date.
 - e) Quantity, unit and package size.
 - f) Name, nationality and address of the manufacturer.
3. The certificate of origin certified by the chamber of commerce at the country of origin or the exporting country.
- The certificate should state the product name, batch number and quantity, name and nationality of the manufacturer or otherwise, the number and date of the invoice.
4. A valid copy of the manufacturer license where the process of secondary packaging will be conducted.
5. A certificate of analysis for each batch issued and certified by the quality manager at the manufactory, if the local manufacturer is responsible for the secondary packaging and the Release process is conducted by the foreign manufacturer.
6. A copy of the Bill of lading.
7. A copy of the custom statement.

11. Requirements & Regulations for Active Pharmaceutical Ingredients (A.P.I.) Clearance for Local Manufactures

- **Regulations:**

- 1- If the imported chemicals are precursors or subject to control by the General Directorate of Public Security, Clearance requirements for such products are applied.
- 2- Clearance shall be granted to the manufacturer or licensed warehouse which is intended to trade in chemicals
- 3- Containers shall have labels which include the information of the transported substances and storage and transport conditions.
- 4- Storage and transport shall be in accordance with what mentioned in the label.
- 5- The importer shall fully comply with Practices of good distribution and storage guideline.
- 6- Submit all required documents to the Drug Sector Office at the port of arrival.

- **Documents to be Submitted for Clearance:**

- 1- A letter to SFDA requesting a clearance approval stating the following:
 - a) The imported chemical substances information.
 - b) Purpose of importing.
 - c) A pledge (an obligation) stating that the imported chemicals will be used inside the manufactory and under their responsibility. Also if it's for a warehouse the chemicals will be under their responsibility.

- 2- A certified invoice containing all information for chemicals which are intended to be cleared.
- 3- A certified certificate of origin.
- 4- A certificate of analysis including, but not limited to, the following:
 - The manufacturer's site.
 - Batch No.
 - Batch size / type
 - Date of manufacturing.
 - Expiry date or re-test period.
 - Test method, result and specifications
- 5- A valid copy of the manufacturer or warehouse license issued by SFDA
- 6- A valid copy of the bill of lading.
- 7- A valid copy of the import statement.

12. Regulation and Requirements for Importing and Clearance of Medications for Compassionate Use

First: Importing Medication for Compassionate Use:

- **Regulations:**

1. Approval of SFDA Drug Sector for the Compassionate Use medication.

- **Requirements:**

1. A letter from the beneficiary to SFDA Drug Sector, include a request for import approval for the medications and stating the following:
 - a) Purpose of importing the medications and the name(s) of the patient(s) who will use these medications.
 - b) All required information for the medications to be imported:
 - 1) Medications names.
 - 2) Concentration and pharmaceutical form.
 - 3) Quantity, unit, and package size.
 - 4) Name and nationality of the manufacturer.
 - 5) Name of the importer.
 - c) The following phrase shall be written in the letter:

“Importing of these Medications will be under our responsibility, and it will only be used for the patients approved in the Compassionate Use Program, and in case of refusing the acceptance of the medications for any technical reason or for not matching the specifications and terms of importing, we will detain the quantity and notify the Authority, and we will not give it to any other agency without SFDA approval”.
2. Attach a copy of the SFDA approval for the compassionate use program of these medications.

Second: Clearance of Medication for Compassionate Use

- **Regulations:**

1. A valid importing license from Drug Sector.
2. Full compliance with “**Regulation of Transporting and Storing Medication and Pharmaceutical Products Through Customs Ports**” which are published at SFDA website.
3. A Data logger should be placed to register the temperature of the shipment according to what mentioned in the related guideline and approved Data logger specifications. **Also, the serial number of the Data logger should be written in one of the shipment documents.**
4. Submit all required documents to the Drug Sector Office at the port of arrival.

- **Requirements:**

1. A letter from the Importer submitted to SFDA Drug Sector office at port of arrival, include a request for clearance approval for the medications and state the following:
 - a) The purpose for clearance, with defining the beneficiary which will execute the compassionate use program.
 - b) Port of arrival and the number of the invoice and bill of lading.
 - c) A pledge for delivering the medications to the beneficiary which will execute compassionate use program.
 - d) All information of the medications which intended to be cleared as following:
 - Medications names.
 - Concentration and pharmaceutical form.
 - Quantity, unit and package size.
 - Name and nationality of the manufacturer.
 - Name of the importer.
2. Attach a copy of the valid importing license from Drug Sector.
3. The original invoice of the manufacturer or the marketing company certified by the chamber of commerce at the country of origin or the issuing country.

The invoice should include the following information:

- a) The invoice number and date.
 - b) Trade name of the medications.
 - c) Concentration and pharmaceutical form.
 - d) Batch number, production date and expiry date.
 - e) Quantity, unit, and package size.
 - f) Name, nationality and address of the manufacturer.
 - g) Name of the beneficiary which will execute the compassionate use program, or the purpose for clearance.
4. A copy of bill of lading.
 5. A copy of Custom statement.

13. Regulations and requirements for Listed Products Clearance

Listed Products: any products which had been listed at the SFDA and accordingly were issued a listing number and certificate.

Regulations:

- 1- Importing products process must be done in accordance with the registered specifications of which the most important are:
 - l) Printing the listing number and the importer's name on the package.
 - m) Writing the product data in Arabic language on the package.
 - n) Printing the production date, expiry date and batch no. on the package.
- 2- Imported products should have at least 70% remaining of their shelf life.
- 3- Full compliance with “**Regulations of Transporting and Storing Medication and Pharmaceutical products through Customs Ports**” which are published at SFDA website.
- 4- A Data logger should be placed to register the temperature of the shipment according to what mentioned in the related guideline and approved Data logger specifications.
- 5- Samples will be taken from the first shipment and the importer will sign a written pledge (obligation) stating that such products will not be used; the pledge (obligation) form is available at the SFDA website.

If another shipment arrives before issuing the analysis results of the first shipment and there aren't any defects about it, the shipment shall be cleared by a written pledge (obligation) from the importer state that they will not use these products until the results of first shipment samples are issued.
- 6- Submit all required documents to the Drug Sector Office at the port of arrival.

• **Documents to be Submitted for Clearance:**

- 1- A letter requesting the clearance from the importer stating the number of invoice and the bill of lading.

- 2- The original invoice of the manufacturer or the marketing company (as mentioned in the listing certificate) certified by the chamber of commerce at the country of origin or the exporting country.
The invoice should include the following information:
 - f) The invoice number and date.
 - g) Products trade name and the pharmaceutical form.
 - h) Batch number, production and expiry date.
 - i) Quantity, unit and package size.
 - j) Name, nationality and address of the manufacturer.
- 3- The certificate of origin (original copy) certified by the chamber of commerce at the country of origin or the exporting country.
- 4- A certificate of analysis for each batch issued and certified by the quality manager at the manufactory.
- 5- A valid copy of the product's listing certificate which has been issued by the SFDA.
- 6- A copy of the bill of lading.
- 7- A copy of the custom statement.

14. Regulations and Requirements for Importing and Clearance of Medications and Medical Supplies for Clinical Trials

First: importing medications and Medical supplies for clinical Trials:

- **Regulations:**

2. A valid approval of SFDA Drug Sector for the clinical Trials.

- **Requirements:**

3. A letter from the beneficiary, which will practice the clinical Trials, including a request for importing approval to be submitted to Drug Sector headquarters, and state the following:

- d) The purpose of importing medications / medical supplies, and the clinical trials that will be used for it.

- e) All information for the medications / medical supplies to be imported:

1. The medications / medical supplies names.
2. Concentration of the medication and pharmaceutical form
3. Quantity, unit, and package size.
4. Name and nationality of the manufacturer.
5. Name of the importer.

- f) The following phrase shall be written in the letter:

Importing these medications / medical supplies will be under our responsibility, and it will only be used in the approved clinical trials, and in case of refusing the acceptance of the medications / medical supplies for any technical reason or for not matching the specifications and terms of importing, we will detain the quantity

and notify the Authority, and we will not give it to any other agency without SFDA approval.

4. A valid copy of SFDA approval for the clinical trials.

Second: Clearance of medications / Medical supplies for clinical trials:

- **Regulations:**

5. A valid importing license from Drug Sector.
6. Full compliance with transport and storage conditions which are published at SFDA website.
7. A Data logger should be placed to register the temperature of the shipment according to what mentioned in the related guideline and approved Data logger specifications. **Also, the serial number of the Data logger should be written in one of the shipment documents.**
8. Submit all required documents to the Drug Sector Office at the port of arrival.
9. Full compliance with requirements of Saudi Food & Drug Authority, regarding labeling and packaging of medications to be used in clinical trials, which mentioned in the circular No. 26653, dated on 2/12/1432 A.H [29-october-2011] (a copy of the circular is attached).

- **Requirements:**

6. A letter from the Importer submitted to SFDA Drug Sector office at port of arrival include a request for clearance approval for medications / medical supplies and state the following:
 - e) The purpose of clearance and the clinical trials that will be used for it.

- f) Port of arrival and the number of the invoice and bill of lading.
 - g) A Pledge for delivering the medications / Medical supplies to the beneficiary which will practice the clinical Trials.
 - g) All information's of the medications which intended to be cleared as following:
 - Medications / Medical supplies names.
 - Concentration of the medication and pharmaceutical form.
 - Quantity, unit and package size.
 - Name and nationality of the manufacturer.
 - Name of the Importer.
7. A valid copy of the importing license from Drug Sector.
8. The original invoice of the manufacturer or the marketing company certified by the chamber of commerce at the country of origin or the issuing country.
- The invoice should include the following information:
- h) The invoice number and date.
 - i) Trade name of the medications / Medical supplies.
 - j) Concentration and pharmaceutical form.
 - k) Batch number, production date and expiry date.
 - l) Quantity, unit and package size.
 - m) Name, nationality and address of the manufacturer.
 - n) Name of the beneficiary practice the clinical Trials or the purpose for clearance.
9. A copy of the bill of lading.
10. A copy of Custom statement.



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المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

(٢٥٥)
قطاع الدواء

مرفق رقم (١)

متطلبات البيئة العامة للغذاء و الدواء لبطاقة و تغليف عينات الأدوية المستخدمة في الدراسات
السريية

SFDA requirements for Labeling and Packaging for investigational medicinal products (IMP)

Labeling and Packaging Requirements:

I. The following information should be included on labels unless its absence can be justified:

1. Name, address and telephone number of the sponsor, contract research organization or investigator (the main contact for information on the product, clinical trial and emergency unblinding);

1.1 The address and telephone number of the main contact for information on the product, clinical trial and for emergency unblinding need not appear on the label where the subject has been given a leaflet or card which provides these details and has been instructed to keep this in their possession at all times.

2. Pharmaceutical dosage form, route of administration, quantity of dosage units. And in the case of open trials, the name/identifier and strength/potency;

3. The batch and/or code number to identify the contents and packaging operation;

4. A trial reference code allowing identification of the trial, site, investigator and sponsor if not given elsewhere;

5. The trial subject identification number/treatment number and where relevant, the visit number;

6. The name of the investigator (if not included in (1) or (1.1));

7. Directions for use (reference may be made to a leaflet or other explanatory document intended for the trial subject or person administering the product);

8. "For clinical trial use only" or similar wording; (Arabic & English)

9. The storage conditions;

10. Period of use (use-by date, expiry date or re-test date as applicable), in month/year format and in a manner that avoids any ambiguity.

11. "Keep out of reach of children" except when the product is for use in trials where the product is not taken home by subjects. (Arabic & English)

المملكة العربية السعودية - الرياض ١٢٣١٢ - ٦٢٨٨ - حي النفل - ٢٢٩٢ الطريق الدائري الشمالي - هاتف: ٩٦٦ ١ ٢٧٥٢٢٢ - فاكس: ٩٦٦ ١ ٢٠٥٧٦٢٣
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II. When the product is to be provided to the trial subject or the person administering the medication within an immediate container together with outer packaging that is intended to remain together, and the outer packaging carries the information listed in section I, the following information shall be included on the label of the immediate container (or any sealed dosing device that contains the immediate container):

1. Name of sponsor, contract research organization or investigator;
2. Pharmaceutical dosage form, route of administration (may be excluded for oral solid dose forms), quantity of dosage units and in the case of open label trials, the name/identifier and strength/potency;
3. Batch and/or code number to identify the contents and packaging operation;
4. A trial reference code allowing identification of the trial, site, investigator and sponsor if not given elsewhere;
5. The trial subject identification number/treatment number and where relevant. The visit number.

III. If the immediate container takes the form of blister packs or small units such as ampoules on which the information required in section I cannot be displayed, outer packaging should be provided bearing a label with those information. The immediate container should nevertheless contain the following:

1. Name of sponsor, contract research organization or investigator;
2. Route of administration (may be excluded for oral solid dose forms) and in the case of open label trials, the name/identifier and strength/potency;
3. Batch and/or code number to identify the contents and packaging operation;
4. A trial reference code allowing identification of the trial, site, investigator and sponsor if not given elsewhere;
5. The trial subject identification number/treatment number and where relevant, the visit number.

IV. Symbols or pictograms may be included to clarify certain information mentioned above.

Additional information, warnings and/or handling instructions may be displayed.



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- V. During packaging of investigational medicinal products, it may be necessary to handle different products on the same packaging line at the same time. The risk of product mix up must be minimized by using appropriate procedures and/or, specialized equipment as appropriate and relevant staff training.
- VI. Packaging and labeling of investigational medicinal products are likely to be more complex and more liable to errors (which are also harder to detect) than for marketed products, particularly when "blinded" products with similar appearance are used. Precautions against mis-labelling such as label reconciliation, line clearance, inprocess control checks by appropriately trained staff should accordingly be intensified.
- VII. The packaging must ensure that the investigational medicinal product remains in good condition during transport and storage at intermediate destinations. Any opening or tampering of the outer packaging during transport should be readily discernible.



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الهيئة العامة للغذاء والدواء
(٢٥٥)
قطاع الدواء

مرفق رقم (٢)

متطلبات الهيئة العامة للغذاء والدواء لبطاقة و تغليف عينات الأدوية المستخدمة في الدراسات السريرية

SFDA requirements for Labeling and Packaging for investigational medicinal products (IMP)

I. Outer Label Text

Clinical Trial No.
Drug Name and Strength
Dosage form
Specific description for syringe content
Route of Administration
Storage condition
Lot No.
Expiry Date
Expiry Date(Arabic)
Use as directed
Warning: For Clinical Trial Use only.
Warning: For Clinical Trial Use only.(Arabic)
Manufacture name , city, country

II. Inner Label Text

CT No. Visit number: Visit Date: dd/mm/yyyy Patient No.:	For Clinical Trial use only	CT No. For Clinical Trial Use only Visit number: Visit Date: dd/mm/yyyy Patient No.: Drug Name Strength Dosage form, Route of administration
	Please keep out the reach and sight of Children	
	Drug Name Strength	
	Dosage form, Route of administration	
	Use as directed	
	Investigator/_____	
	Telephone No./_____	
	Do not store above ____ °C (...F)	
	Expire Date: marked on the folding box	
	Lot No./	

III. Export

1. Regulations & Requirements for Exporting Human Drugs, Health and Herbal Products and Cosmetics

- **Regulations:**

- 1- The Exporting Request should be submitted directly by the manufacturer.
- 2- Each export request should be submitted to the main headquarters of the drug sector.

- **Requirements:**

- 1- A letter from the manufacturer to Saudi Food & Drug Authority – Drug Sector stating the following:
 - a) The name of the exported Products.
 - b) The registration number for the registered products.
 - c) Quantity, unit and package size.
 - d) Batch number.
 - e) Total value in Saudi Riyals.
 - f) Transportation process.
 - g) Exporting port.
 - h) The beneficiary and its address.
 - i) The Expected date for export.
- 2- A copy of the invoice issued to the beneficiary.
- 3- A copy of the Manufacturer license.

2. Regulations and Requirements for Re-Exporting Human Drugs, Health and Herbal Products and Cosmetics

Re-Exporting: It is the exporting of products which had been imported to be used in Saudi Arabia, and the request for the re-export should state the reasons and justifications for it.

- **Regulations:**

1. The re-exporting request should be submitted directly by the Agent.
2. Each export request should be submitted to the main headquarters of the drug sector.
3. If the product that is intended to be re-exported is registered in Saudi Arabia, the registration data on the packages must be removed.

- **Requirements:**

1. A letter for product re-exporting from the agent to Saudi Food & Drug Authority – Drug Sector to re-export such products, stating the following:
 - a) The name of the re-exported Products.
 - b) The registration number for the registered products.
 - c) Quantity, unit and package size.
 - d) Batch number
 - e) Total value in Saudi Riyals.
 - f) Transportation process.
 - g) Exporting port.
 - h) The beneficiary and its address.
 - i) The Expected date for export.
 - j) Reasons and justifications for re-exporting.

2. A copy of invoice, issued to the beneficiary.
 3. A statement from the electronic system of the warehouse, Indicate the remaining quantities in the warehouse after re-exporting, and clarify that these quantities are sufficient for the local market for minimum of six months.
- **It is prohibited to re-export the damaged or counterfeited products, and they must be disposed by specialized companies, in attendance of an inspector from Drug Sector.**

- Regulations of Transporting and Storing Medication and Pharmaceutical Products Through Customs Ports

First: the customs ports where medication, Pharmaceutical products, and cosmetic are allowed to enter from:

1. King Khaled International Airport in Riyadh.
2. King Abdulaziz International Airport in Jeddah.
3. King Fahd International Airport in Dammam.
4. Prince Mohammad Bin Abdulaziz Airport in Madinah.
5. King Abdulaziz International Airport in Dammam.
6. King Abdullah Sea Port in Rabigh.
7. Jeddah Islamic Sea Port.
8. Riyadh Dry Port.
9. Batha Port.
10. King Fahd Causeway.
11. Khafji Port.
12. Haditha Port.
13. Tuwal Port.
14. Salwa Port.

Blood products,
Vaccines and
medications which
need a storage
temperature less than
8°C are allowed to
enter from these
ports only.

- Controlled, narcotic, or psychological medication shall **only** be **allowed** to enter through the above-mentioned airports.

Second: Regulations of transportation and storage for medications, pharmaceutical products, listed products and the imported products for the purpose of secondary packaging in the local manufacturer (BULK):

1. Importing and clearance of these medications and pharmaceutical products must be conducted only through the approved ports by SFDA Drug Sector.
2. Medications and pharmaceutical products must be imported and transported in refrigerated containers.
3. Data loggers must be available in the medications and pharmaceutical products shipments and the serial number of the Data loggers should be written in one of the shipment documents as per the following:
 - a) If the size of the shipment was less than a pallet, one Data logger at least shall be provided to measure the storage temperature of each

- package in the shipment and shall be activated from shipping time from the manufacturer country till arriving to the Saudi port.
- b) If the shipment was in the same size of pallet and the storage temperature for the pallet shall be maintained as it in one system it will be treated as a package and one Data logger at least shall be provided to measure the temperature in each pallet of the shipment, and the Data logger shall be placed in the most exposed place to the high temperature; but if the storage temperature is fixed in each pallet, each pallet shall contain one Data logger at least.
 - c) If the shipping is in refrigerated containers, it will be treated as one pallet and one Data logger at least shall be set to measure the temperature in the refrigerated container, The Data logger must be placed in the most exposed place to the high temperature.
 - d) All shipments that will transport to the agent warehouses shall contain an additional Data logger to measure the temperature in order to monitor temperature during transfer operations from the port till storing in the warehouse.
- 4. If the products are affected by the humidity, a Data logger to measure the humidity percentage must be attached.
 - 5. After completing the process of inspection and clearing the shipment, the shipment should be transported and stored in the agent warehouses according to the transport and storage conditions recommended by the manufacturer.
 - 6. Temperature reading records must be kept in the warehouse in private registries that shall be presented to the inspectors of the SFDA at the periodic visits or as necessary.

Third: The regulation of transportation and storage for Cosmetic, chemicals, and raw plant:

- 1. Importing and clearance of these products must be conducted only through the approved ports by SFDA Drug Sector.
- 2. The Importation and transportation must be conducted in containers according to the transport and storage conditions recommended by the manufacturer.

3. After inspection and clearing the shipment, the shipment should be transported and stored in the agent warehouses according to transport and storage conditions recommended by the manufacturer.
4. Activated Data loggers must be placed with the shipment and be read in the port of arrival and in the importer warehouses. Temperature reading records must be kept in private registries.

Fourth: the specifications of indicators required to be provided to measure the temperature in the shipments.

Data Logger Specifications

- **Physical Requirements:**

1. LCD display of temperature, digital readout, for instant checks and to ensure logger set up has been activated.
2. Indication of active logging, Alarm function with programmable limits with audible/visible alarm warning.
3. Setup with start/stop functionality.
4. Temp. Accuracy Range ($\leq 1^{\circ}\text{C}$).
5. Humidity Accuracy Range ($\leq 4\%$).
6. Robust construction, waterproof.
7. Long battery life with integral battery life indicator (at least 6 month).
8. Temp. & Humidity recording at least for 180 Days.
9. Monitor Recording Options (Single use or multi use, internal sensor).
10. Integrated USB connector; no hardware or interface cable required.

- **Software Requirements:**

1. Temp. Measurement Range (-30°C to 70°C).
2. Humidity Measurement Range (0% to 100%)
3. Appropriate software should be provided to enable set up and download of information from logger to PC application (Easy-to-use “plug-n-play” operation, no PC applications and no retained PC “footprint”)

4. Software should allow data to be stored, displayed and/or printed in tabular and graphical form (automatic generation of Adobe PDF report, can be saved and sent).
5. Software should be compatible with minimum PC Specification.