



Requirements

of transport and storage of pharmaceutical products subject to the supervision of the drug sector through customs ports

Version no 1.3

Vision and Mission of the Saudi Food and Drug Authority



Our vision...

To be a leading global body based on scientific foundations to promote and protect public health



Our mission...

Protecting society through legislation and an effective regulatory system to ensure the safety of food, medicine, medical devices, cosmetic products, pesticides, and feed

Documentation

Version	Date	Publisher	Remarks
1.0	18 th August 2015	Port management	Final version
1.1	28 th March 2018	Port management	Update
1.2	22 nd June 2021	Clearing Management and Port Support	Update
1.3	09 th January 2024	Clearing Management and Port Support	The following page describes the terms of the update

What is the update of this version (Number 1.3)?

Below is a table showing the updates:

Title	Type of update
2. Transportation and storage conditions	<p>Update:</p> <p>All shipments shall contain an additional indicator to measure temperatures through which temperatures shall be monitored during transport operations from the port and until storage in the warehouses of the supplier or beneficiary (the additional indicator does not need to be of the same specifications as required by the Authority, and its reading and retention data shall be printed It is stored in the warehouse for a period of one year after the expiry date for products imported from the same consignment in special records that shall be reviewed by the Authority’s inspectors during periodic visits or if necessary). In the case of using indicators that use the Internet (web datalogger) or cloud services (cloud datalogger), there is no need for an additional indicator in the consignment, and only one is sufficient.</p>
3. Specifications of temperature measurement indicators required to be provided in shipments:	<p>Addition:</p> <p>3.3 Software requirements</p> <p>Cancellation:</p> <p>3.2.4 The construction of the indicator is solid and waterproof</p> <p>Amendment:</p> <p>3.2.4 The ability of the indicator to record temperatures for a period ranging from 100 to 180 days or the duration of transporting the product from the place of activation of the reader in the shipping stage to the licensed warehouses at the storage headquarters “whichever is higher”.</p>



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1. Ports through which medicines and pharmaceutical preparations are allowed to enter:

1. King Khalid International Airport in Riyadh.
2. King Abdulaziz International Airport in Jeddah.
3. King Fahd International Airport in Dammam.
4. Prince Mohammed bin Abdulaziz Airport in Medina.
5. King Abdulaziz Port in Dammam.
6. King Abdullah Port in Rabigh.
7. Jeddah Islamic Port.

(Serums, vaccines and medicines that require preservation temperatures below 8 degrees Celsius are allowed to enter only through these ports)

8. Riyadh Dry Port.
9. Batha outlet.
10. King Fahd Causeway port.
11. Khafji port.
12. Al Hadithah Land Port.
13. Twal port.
14. Salwa port.

- **Controlled drugs, narcotics and psychotropic drugs are only permitted to enter through the airports indicated above.**



2. Conditions of transportation and storage:

2.1 Conditions for transport and storage of medicines, pharmaceutical preparations, listed preparations and imported preparations for the purpose of secondary packaging in local human and veterinary factories (BULK), samples and standard materials:

2.1.1 Shipments shall be supplied through Approved ports by the Authority.

2.1.2 Medicines and preparations shall be supplied directly from the country of origin or according to what is registered In SFDA and SFDA does not allow the supply from free zones.

2.1.3 All above mentioned point (2,1) of the Kingdom shall be supplied and transported with refrigerated containers

2.1.4 Indicators to measure temperature as described below shall be placed in all imported shipments, and they shall be activated from the departure of the shipment from the country of origin until they arrive at the port.

- If the size of the shipment is less than a pallet, at least one indicator shall be provided to measure the temperature in each package of the shipment.
- If the size of the shipment is the size of a pallet and its temperature is maintained by one system, it is treated as a parcel, and at least one indicator shall be placed to measure the temperature in each pallet of the shipment, and the indicator shall be placed in the place most susceptible to temperature rise.

- If the temperature is maintained in each package separately, each package shall contain at least one indicator.
- If the shipment is in refrigerated containers, they are treated as one pallet, and at least one indicator shall be placed to measure the temperature in the refrigerated container, and the indicator shall be placed in the place most susceptible to temperature rise.
- All shipments shall contain an additional indicator to measure temperatures through which temperatures shall be monitored during transport operations from the port and until storage in the warehouses of the supplier or beneficiary (the additional indicator does not need to be of the same specifications as required by the Authority, and its reading and retention data shall be printed. It is stored in the warehouse for a period of one year after the expiry date for products imported from the same consignment in special records that shall be reviewed by the Authority's inspectors during periodic visits or if necessary). In the case of using indicators that use the Internet (web datalogger) or cloud services (cloud datalogger), there is no need for an additional indicator in the consignment, and only one is sufficient.
- The serial number of the indicators shall be written in one of the shipment documents.

2.1.5 If the products are affected by humidity, they shall be accompanied by indicators to read the humidity level.

2.1.6 The shipment shall be adhered to and stored in accordance with the transportation and storage conditions recommended by the manufacturer from the time it is shipped from its source until it reaches the port of entry and the issuance of the final clearance decision and then transported to the warehouses of the supplier or beneficiary party.

2.2 Conditions for transportation and storage of cosmetic products and chemicals:

2.2.1 The supply shall be made with containers through which the supplier guarantees transportation and storage in accordance with the conditions recommended by the manufacturer. The Authority does not permit the use of means of transportation that do not protect the products from exposure to high temperatures and humidity or from exposure to direct air (such as open means of transportation or covered with sails).

2.2.2 The shipment shall be transported and stored in accordance with the transport and storage conditions recommended by the manufacturer from the time it is shipped from its source until it reaches the port of entry and the issuance of the final clearance decision, and then transport it to the warehouses of the supplier or beneficiary.

2.3 Conditions for transportation and storage of raw medicinal plants

2.3.1 Shipments shall be supplied through Approved ports by the Authority.

2.3.2 The quality of raw medicinal plants shall be maintained during the transportation process, and safety requirements shall be taken into account in transporting medicinal plants while adhering to the following requirements:

- Containers (packing units) shall be clean and dry.
- The containers (packing units and means of land, sea and air transport) shall be suitable for transporting raw medicinal plants, taking into account the requirements of the condition of the transported plant (dry or fresh) with regard to temperature, ventilation and humidity according to the following:
 - The fresh plant shall be transported in transport units that provide sufficient and appropriate ventilation, taking into account the absence of exposure to light, dust, rain and high temperature in accordance with the conditions and requirements of each plant.
 - The dry plant shall be transported in transport units that protect it from moisture, taking into account the absence of exposure to light, dust, rain, and high temperature, according to the conditions and requirements of each plant.

2.3.3 The importer shall commit to storing it according to the storage conditions appropriate to the condition and type of plant and contained in scientific principles and standards, taking into account expediting clearance procedures and speeding up its transportation to warehouses.

2.3.4 The shipment shall be transported and stored upon its arrival at the port of arrival and after the Authority's decision to release it according to the recommended transport and storage conditions, whether in the importer's or the beneficiary's warehouses.



3. Specifications of temperature measurement indicators required to be provided in shipments

3.1 General requirements:

3.1.1 The accuracy of measuring temperatures for the indicator (+\ -1 degree Celsius).

3.1.2 Temperature measurement range (-30) to 70 degrees Celsius.

3.1.3 The humidity measurement accuracy of the indicator is less than or equal to 4%).

3.1.4 Humidity measurement range (0% to 100%)*.

3.1.5 There are options for ways to follow up on recordings, single use or multiple times

3.1.6 The indicator's ability to record temperatures and humidity for a period of no less than 180 days.

If the preparations are based on the manufacturer's recommendations, they shall be stored away from moisture or the products will be transported at any stage of transportation by sea.

3.2 Indicator specifications:

3.2.1 The screen displays temperature readings so that the indicator is activated and known readings upon shipment arrival.

3.2.2 Indicator to prove active recording, with audio and/or visual alarm feature and adjustable temperature limits to activate the alarm.

3.2.3 On and off feature.

3.2.4 The ability of the indicator to record temperatures for a period ranging from 100 to 180 days or the duration of transporting the product from the place of activation of the reader in the shipping stage to the licensed warehouses at the storage headquarters "whichever is higher".

3.2.5 The indicator has a (USB) port.

3.3 Software requirements

3.3.1 A suitable program allows transferring temperature measurements from the indicator to a computer application directly (There is a direct plug and play feature) without the need for special software.

3.3.2 In the event of using indicators that use the Internet (web datalogger) or cloud services (cloud datalogger), the Authority shall be provided with the user name, password, and website where the readings can be viewed.

3.3.3 The software shall allow storage, display and/or printing in tabular or graphical form (The ability to save and send reading reports in the form of a PDF file).

3.3.4 The device driver shall be compatible with computers with the lowest specifications

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