

## 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 (attached).**

### **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 ( $-30^{\circ}\text{C}$  to  $70^{\circ}\text{C}$ ).
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.