

Frequent issues regarding shipments to Saudi Arabia

For any information regarding

The Regulation and Requirements for Clearance and Export

Regulations of Transporting and Storing Medication and Pharmaceutical products through Customs Ports

Visit www.sfda.gov.sa

Contact us By E-mail Ports.Drug@sfda.gov.sa

□ NON- Compliance with Saudi FDA Regulations of Transporting and Storing Medication and Pharmaceutical products through Customs Ports: (like the following)

- Transporting in a non-temperature controlled containers.
 - Transport and Storing conditions are not suitable for the shipped products.
 - Not placing the required amount of data loggers in the shipment.
 - Using Data Loggers that does not comply with SFDA specification for data loggers. - Placing a Data Loggers without activation.
 - Stoppage of the Data Loggers recording before shipment arrival to the agent warehouse.
 - **NON- Compliance with Saudi FDA Clearance Requirements:**
 - **Issues regarding the outer pack, like not printing the following:**
 - Saudi registration number and public price (IN ARABIC.) ⁽¹⁾
 - Products information (IN ARABIC). ⁽¹⁾
 - Storage conditions (IN ARABIC). ⁽¹⁾
 - Manufacturing company name and nationality. ⁽¹⁾
 - Manufacturing and expiry date according to The GCC Guidance for Presenting the SPC, PIL and Labeling Information. ⁽¹⁾
 - (FOR ANIMAL USE ONLY) on the outer pack for the veterinary medications (IN ARABIC). ⁽¹⁾
 - The phrase (Free medical samples) on the outer pack for the products that intended for medical samples (IN ARABIC). ⁽¹⁾
 - **The non-compliance with the following:**
 - Tamper proof and plastic sealed cap for the liquids plastic and glass bottle.
 - Label Information on the outer pack as specified by SFDA.
 - Manufacturing or marketing company invoice requirements.
 - Printed price and/or Shelf life on the outer pack does not match what registered in SFDA⁽¹⁾.
 - Printing the data logger's serial numbers in one of the shipment documents.
- ❖ **The issues mentioned above, may result in shipment delay or rejection the clearance.**

(1) This requirement is for products registered in Saudi Arabia only.