

Frequently Asked Question for Temperature Monitors

Q1) Where data loggers of temperature monitors shall be placed? (in each container or each pallet or each single carton)?

Answer: For products that are sensitive to temperature changes (less than 8°C), the monitor must be placed in each pallet. However, if the shipment is not pallet size, each outer case must contain a temperature indicator. If the manufacturer's SOP requires more indicators to be placed in the shipment then that SOP should be followed.

For products shipped in controlled cold containers and are not highly sensitive to temperature changes (room temperature condition), at least one monitor must be placed in the container. However, the monitor must be placed in the hottest spot in the container based on temperature mapping.

Q2) As there is no temperature control in airports and shipments may be kept outside of cold room for a while in direct sunlight, how can the distributor guarantee that the temperature of the products will not rise and how long will it take the Saudi FDA representative to check and read all data loggers received?

Answer: SFDA inspectors work from 7:30am till midnight to make sure there is no delay in pharmaceuticals clearance. However, it is the distributor's responsibility to clear shipments quickly with the Airlines and Customs.

Q3) Are the temperature monitors required for sea and truck shipments, if the products are shipped using cold containers? Is it required to place data loggers or temperature monitors with the shipment?

Answer: Yes it is required for all shipments. (please see Q1)

Q4) Does the temperature excursion reported by monitors justify rejection of the full shipment?

Answer: according to SFDA requirements, all pharmaceutical shipments must be shipped in containers that match manufacturer specifications for storage. Any shipment that does not comply with these conditions will be rejected by SFDA. Moreover any temperature excursions are subject to further investigation according to the manufacturer's stability data in the registration file at SFDA.

Q5) Are controlled cold containers (refer. Container) mandatory for all shipments?

Answer: controlled cold containers and temperature monitors are mandatory for all sea and ground transportation shipments. On the other hand, controlled cold containers are not

mandatory for airfreight shipments; however supplier must ensure that goods are packed in suitable protective packaging which keeps the temperature within the required limits.

Q6) Are the data loggers in each pallet needed if the containers are shipped via sea freight, and the products only require room temperature storage conditions?

Answer: Products shipped by sea must be shipped in controlled cold containers and if the products are not highly sensitive to temperature changes (room temperature condition), one monitor must be placed in the container. However, the monitor must be placed in the hottest spot in the container.

Q7) If SFDA representatives stop the data loggers upon shipment arrival, there will be no temperature monitoring during the time spent at the custom?

Answer: The SFDA understands this issue and will open a very limited number of cartons (randomly) to check shipments and collect monitors. However, suppliers may choose to include extra monitors in each shipment, clearly marked ((FOR SFDA USE)), the other monitors will cover the remainder of the trip.

Q8) Is the requirement for controlled cold containers and temperature monitors applicable to bulk and active ingredients?

Answer: This Process is applicable only to finished products. Active ingredients are considered as chemicals and will not be covered by these regulations. Bulk is considered a semi-finished product and will be treated as finished product.

Comments

1. Suppliers are requested to advise the SFDA in regards to the type of monitors/software/download device, enabling the SFDA to make it available.
2. SFDA inspectors are available from 7:30am and on duty till midnight, Distributors must notify SFDA with arrival details in ample time to facilitate a speedy clearance process.
3. Importing Batch-Release and Clearance System (IBRCS) is available and supplier are allowed to access under a sub-account to their local distributors (to inform SFDA of arriving shipments)