الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Frequently Asked Question for Temperature Monitors

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Saudi Food & Drug Authority

Drug Sector

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Saudi Food and Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

Q1) Where data loggers for 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 8ºC), 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 (passive or active) that are not highly sensitive to temperature changes (room temperature conditions), at least two data loggers must be placed in the container; the first one should be checked by SFDA inspectors and the other one in the importer's warehouses. However, the data loggers 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 inspectors to check and read all data loggers received?

Answer: SFDA inspectors work around the clock to make sure there is no delay in pharmaceuticals shipments 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 cold 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 (passive or active) **(refer. Container) mandatory for all shipments?**

Answer: controlled cold containers (active) and temperature monitors are mandatory for all sea and ground transportation shipments. On the other hand, controlled cold containers (passive or active) are mandatory for airfreight shipments; 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 place in the container. However, the monitor must be placed in the hottest spot in the container based on the temperature mapping.

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

Answer: The importer must include more than one data logger to be checked by SFDA inspectors at the arriving port and the other at the importer's warehouse.

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 the regulations for Guidance for the Storage and Transport of Pharmaceutical Products throughout the customs port. Bulk is considered a semi-finished product and will be treated as finished product.

Q9) Does the specification of cloud/web data logger different from regular data logger?

Answer: There are no difference in the specification requirement between the two types.

Q10) If I use cloud/web data logger, where can we provide the website and the login info.?

Answer: The website and the login info can be provided in one of the shipment documents or separate documents.

Q11) Do I have to provide the cloud/web data logger serial number also in one of the shipment documents?

Answer: Yes, the serial number of the cloud/web data logger must be provided in one of the shipment documents as same as the regular data logger.

Q12) Are the data loggers should be calibrated when they are used?

Answer: Yes, it should be calibrated and used within the time period for calibration.

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 around the clock, Distributers must notify SFDA with arrival details in ample time to facilitate a fast 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)