CardinalHealth
Essential to care™

Cold Chain Packaging

Limitations of spot temperature testing

Limitations of Spot Temperature Testing

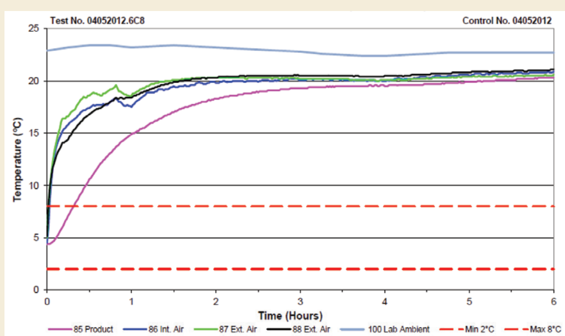
Cardinal Health uses refrigerated totes with a passive coolant system opposed to an active system like a freezer. Active systems respond to rapid temperature changes, such as when a door is opened, by engaging the compressor and fan to replace warm air with cold air until the temperature is brought back within the set range. Passive systems are designed to remain closed until the product is removed for storage. When the phase change panels are initially placed into the totes they are at the optimal temperature to maintain the product within the 2-8°C temperature range for the period of time that the totes are qualified for (cycle time) when exposed to winter or summer temperatures during transportation. Passive coolant systems utilize an energy source and insulation to maintain the desired temperature range. This system utilizes phase change material and expanded polystyrene (EPS) liners with lids, which are contained within the plastic tote. If the tote is opened, the cool air is immediately replaced with warmer air, and the phase change panels may not have enough energy remaining to bring the temperature back within the desired range, especially at the end of the cycle. Therefore, opening the tote, even for as few seconds to place a temperature probe inside and closing it again will not provide realistic results.

Additionally, the use and placement of temperature measuring devices can result in grossly inaccurate readings for several reasons. One of the most unreliable temperature indicators is Infrared (IR) guns. These devices are typically accurate within 2°C (3.6°F) when properly calculated. The IR guns are commonly used to determine heat leaks in construction. Another problem with end of cycle spot temperature testing is related to the surface temperature changes of packaging, such as the common paperboard cartons for pharmaceuticals. Paperboard is porous and has a very low thermal conductivity. Glass, on the other hand, has a high thermal conductivity (more than 6 times that of paperboard). This means that paperboard does not conduct heat well, and it adapts (changes) to new temperature environments very quickly. These properties were demonstrated in certified environmental laboratory scientific tests.

In addition to monitoring and recording the refrigerated and ambient temperatures, the following were recorded:

1. product temperature (thermocouples on liquid filled glass vials),
2. the airspace temperature inside the paperboard carton (thermocouples in the corner dead space), and
3. the outside surface of the paperboard cartons (thermocouples on the outside surface of the box). The products contained in the manufacturer's paperboard carton with the aforementioned probes were placed and held in an environmental chamber until they all reached 4.4°C, at which time they were placed into an ambient lab environment at 22°C.

Cardinal Health product probe temperatures vs. air probe temperatures corrugate carton — minimum product load constant lab ambient (22°C ± 3°C)



The difference between the product temperature and the outside surface of the paperboard carton over time is as follows:

1. At 3 minutes the carton surface temperature had gone above 10°C while the product surface was still below 4.5°C (variance of 5.5°C),
2. At 10 minutes the carton surface temperature was above 16°C and the product was a 6°C (variance of 10°C),
3. At 15 minutes the carton surface temperature rose to 17°C and the product was still below 8°C (variance of more than 9°C),
4. At 30 minutes the carton surface temperature was above 18°C and the product was at 11°C (a variance of 7°C),
5. At 60 minutes the carton surface temperature reached 19°C and the product was at 15°C (a variance of 4 °C),
6. At 120 minutes the carton surface temperature rose above 20°C and the product was approximately 18°C (a variance of 2 °C).

This test clearly demonstrates the impact of the thermo conductivity differences between glass vials (containing liquid product) and the outside of the vials in the paperboard carton surface temperatures. These examples are at the beginning of the qualification time cycle when the product and the environment within the tote are in the 4°C range. Obviously, the temperature inside the tote will be higher (although still below 8°C); closer to the end of the delivery cycle; therefore, carton surface temperature may be above 15°C when removed from the tote as a result of the low thermo conductivity of paperboard, while the product will still be below 8°C. In summary, using an IR gun to determine product temperature at delivery time has compounded inaccuracies due to the device's accuracy as well as the paperboard carton surface versus product temperature variances.

 Lit. No. 1OPS13-3537 (11/2013)