CSafe®
One world. One cold chain. One mission.

‘STORE IN A COOL, DRY PLACE’ ‘BRING TO ROOM TEMPERATURE BEFORE USE’

White Paper

SEPTEMBER 2015

Those two statements will probably be familiar to many of us who actually bother to read product labels or even those who enjoy making an attempt at cooking. Many recipes call for food ingredients, such as fresh meat, that have been held in a refrigerator to be brought up to ‘room temperature’ before cooking. But therein lies a familiar puzzle – what is ‘room temperature’? And what is a ‘cool, dry place’? What’s ‘Cool’? What’s ‘Dry’?

It’s a problem that continues to draw significant attention within the pharmaceutical distribution and storage environment. For some years, we have become familiar with the requirements of what we know as ‘cold chain’ shipping and with it, the need to maintain temperatures between +2°C and +8°C. To many, this has become more straightforward, as providers have developed a range of both active and passive solutions that satisfy the needs of complex international distribution.

But for those products where ‘room temperature’ storage is a requirement, there is a continuous and ever-increasing demand from a wide variety of regulators for manufacturers to ensure the efficacy of products, previously thought not to need temperature control during transportation, storage and distribution. For many manufacturers, this trend in greater scrutiny has become an immense challenge and its not the least because of the pressures caused by over-stretched public health budgets which demand lower product pricing. And in the veterinary products sector, the challenge will become more acute.

If the USP definition of Room Temperature is short and purposeful – ‘The temperature prevailing in a working area’ – then its current definition of Controlled Room Temperature is much less so:

“A temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C that results in a mean kinetic temperature calculated not to be more than 25°C; and that allows for excursions between 15° and 30°C that are experienced in pharmacies, hospitals and warehouses. Provided the mean kinetic temperature remains in the allowed range, transient spikes up to 40°C may be permitted. An article for which storage at controlled room temperature is directed, may alternatively, be stored and distributed in a cool place, unless otherwise specified in the individual monograph or on the label.”

The result of using these more than 10 year-old guidelines has perhaps been to over-engineer a packaging and transportation solution – a costly answer to a problem where lower value products are involved. CRT ranges on product labels have become numerous and often vary across international borders and within an organization. Furthermore, the current USP definition of controlled room temperature (20° to 25°C) has been under discussion for nearly two years with a proposal that it be changed to a vastly different +2°C to +30°C. No decision is in sight, but if accepted, gives an added question to the logistics and distribution sector – do I store a box with a label in my +2°C to +8°C refrigerator or in my +15°C to +25°C room? Who is liable if there is an excursion?

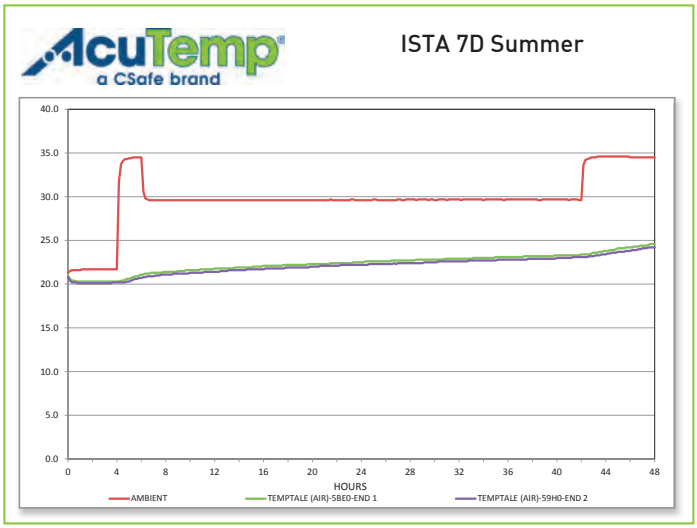
With stability data more widely available, understood and used, obtaining a clear understanding of a product’s true storage and shipping temperature range has become easier. Equally, defining the true ambient profile of the transportation journey through a Performance Qualification (PQ) process using data loggers can create a more cost-efficient solution and based upon reality rather than relying upon a ‘standard’ that is unlikely to cover all the rigors of an international journey. As someone once said, “Let standards be your guide, but let data be your salvation.” One still must consider the ambients to be encountered on new lanes, in new geographies or due to the differing weather patterns being experienced across the globe.

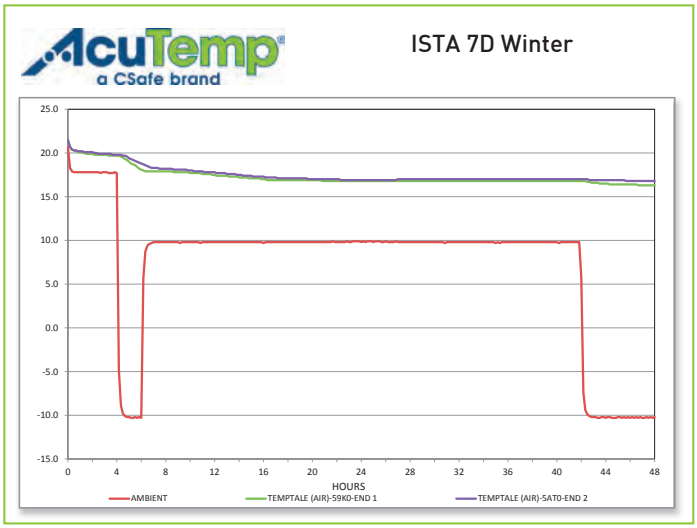
www.CSafeGlobal.com | info@CSafeGlobal.com | Tel: 937-245-6350 | Fax: 937-312-1277

Given that the industry trend seems to be leaning towards a wider temperature tolerance for many pharmaceutical preparations, choosing the right solution in terms of cost, thermal protection and durability is an obvious prerequisite to a product efficacy and profit. In addition, having a range of passive solution sizes from one or two suppliers has become an increasingly valid consideration given that supplier qualification/audit is a fundamental part of the GDP quality management approach.

CSafe has been developing a new range of passive 'shippers' with all this in mind. Though it's a complex mix of requirements, safe and efficient transportation can be achieved. As one of our customers stated, "I cannot compromise on the efficacy of our products, yet I am increasingly challenged to find lower cost solutions that give me the assurance that I will meet regulatory expectations. Normally, these two are not easy neighbors, but the range, quality and overall cost effectiveness of the CSafe product line gives me that confidence."

Controlled Room Temperature 15°-25°C 48 - Hours





About CSafe Global:
CSafe Global is the world's largest producer of actively controlled mobile refrigeration units for biopharmaceutical and healthcare companies, militaries, and international disaster relief agencies. CSafe Global brands include AcuTemp® passive packaging and hand-held mobile carriers, ThermoCor® vacuum insulation and the CSafe® brand of active containers.

The active solution product assortment includes the CSafe RKN, which utilizes heating and compressor-driven cooling technology to eliminate the risks associated with extreme ambient conditions (-30 to +49) as well as the cost, aggravation and environmental challenges associated with dry ice transportation. CSafe Global's AcuTemp brand has provided more than 10,000 hand-held mobile management solutions since its founding more than 25 years ago. The passive solution assortment includes packaging for 2-8°C, CRT and frozen shipments with hold times from 12 to 240 hours and with payload volumes up to 50 liters.

www.CSafeGlobal.com | info@CSafeGlobal.com | Tel: 937-245-6350 | Fax: 937-312-1277