

Introducing the PharmaTherm 15-25 High Performance Profile

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Ever wondered why your 96 hour qualified 15-25 solution goes out of spec after 2 days? Historically, water based 15-25 solutions have been qualified in a different manner than 2-8 solutions. They are not designed to control the temperature between 15-25 degrees, in fact there is very little temperature control going on inside water based 15-25 solution and the qualification process has been adapted to reflect this. If you take the time to compare the qualification reports of a 2-8 and 15-25 solution for the same payload and duration, say 96 hours, you will probably find that a different temperature profile was used in the qualification



process. Yet if you have two shipments, one 2-8 and one 15-25 going to the same destination on the same day you can be pretty sure they are going to experience the same ambient temperatures, so why have they been qualified to different temperature profiles? If you dig a little deeper you will find water based 15-25 solutions provide no specific temperature control, only thermal ballast and insulation. As soon as the shipper is

placed in a different temperature environment, the internal temperature will begin to change. This is because there is no change of phase to absorb the heat energy. If you analyse the temperature profile you may find there is a lot of time spent at 20deg.C with short spikes above and below the 15-25 boundaries. On closer inspection you will see this time is used to recover the internal temperature to prolong the qualified duration.

What Difference Does a Few Degrees Make?

So in order to get your 96hr water based solution to work and last 96hours is to control the logistics environment it is exposed to during transit. This requires working with your logistics vendor to ensure special handling instructions are received and care taken on lane selection. The reality is, if you're using a water based solution and your product cannot experience any temperature deviations, you should be using a dedicated healthcare courier to provide the conditions to which the shipper has been qualified.

The alternative is to use a 15-25 solution that has been qualified to the same temperature profile as the 2-8 shipments, and can handle the external temperatures seen under normal shipping conditions. These will utilise phase change materials and offer true temperature control, there are various forms out there including the cost effective PharmaTherm 15

-25 range by Intelsius. These Pharmatherm are qualified to our high performance temperature profile, a profile we use to qualify our leading 2-8 solutions too. My suggestion is to compare the temperature profile of your 2-8 and 15-25 solutions and the method and mode of transport used to ship and question whether your qualified 15-25 solution and freight method match up.

If you'd like more information on these new products or want to learn more about Intelsius please get in touch with me at david.johnson@intelsius.com or +44 07894 478893.



The INTELSIUS PHARMATHERM insulated shipping systems are designed to offer optimal thermal protection for pharmaceutical products. These shipping systems are pre-qualified to maintain payload integrity during shipments for up to 120+ hours. It is tested against Intelsius' demanding High Performance Dry Ice temperature, 2-8°C profiles and 15-25°C profiles. This test profile is designed to give users confidence that the quality and efficacy of their payloads will not be compromised during even the most demanding of global cold chain shipping lanes.

