

Thermal Risk

HAVE YOU GOT IT

COVERED?

A look at the process of coolchain component qualification in the context of thermal protection and overall transport qualification.



The EU GDP makes it obligatory for manufacturers to ensure that their supply chain partners have the plans, processes and procedures in place to ensure compliance with prevailing regulations relating to product safety. With industry sources* suggesting that up to 5% of pharma transport events are being affected by unwanted temperature excursions there is an urgent need for a better understanding of the role of component qualification to improve temperature management during product distribution.



* 'Handling Temperature Excursions and the Role of Stability Data'. Claude Ammann; Pharmaceutical Outsourcing, September 25, 2013



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Thermal risk - have you got it covered?



A WHITE PAPER FOR PHARMA LOGISTICS

A look at the process of coolchain component qualification in the context of thermal protection and overall transport qualification.

With the manufacture of pharmaceuticals now a global industry and with the new EU GDP and other regulated quality control measures in place, there is a critical need for a structured and stringent validation of the components and solutions used in the transport of pharmaceutical products. One area of particular concern is that of Controlled Room Temperature (CRT) logistics, otherwise known as controlled ambient temperature. The nominal CRT temperature band of 15 to 25° C covers a large proportion of the finished pharmaceuticals that are transported across the world and for this there is a pressing need to put in place CRT management systems that are dependable, effective and affordable. The regulations governing CRT storage and transportation basically require pharmaceutical companies and their distribution partners to take the appropriate

validation and qualification measures to demonstrate coolchain component and system performance and regulatory compliance. The difference between qualification and validation is often confused (see Fig 3 'Validation or Qualification') but in essence they are analogous terms relating to the evidential assurances required as part of a quality management system (QMS) governing the protection of pharmaceutical products during their transport to market.

TANGLED WEB

To bring certainty, consistency and control to the often tangled web of outsource parties involved in pharma distribution requires a coolchain strategy that embraces proven, reliable, thermal-protective technology. With much of the post-production life-cycle of a pharmaceutical product being being literally out of the hands of the manufacturer, it is essential that rigorous carrier and 3PL qualification systems are in place throughout the distribution chain as part of an overall coolchain qualification programme.

To achieve this, the protective component parts and systems used during physical distribution must be suitably qualified and an appropriate control and monitoring programme covering all the possible conditions that might be encountered during each stage of transportation put into effect. Together with other key elements such as dependable tracking systems and certified operative training, a major part of any such a strategy relates to the specification, selection and validation of the discrete coolchain components, equipment and systems that are brought together to form an overall 'qualified shipping lane' or 'GDP compliant' logistical solution.

lanes to demonstrate that the necessary controls are in place to ensure product and, ultimately, patient safety.

This means that all coolchain packaging systems, vehicles and storage facilities, together with all attendant methodologies and operating procedures, need to be approved and performance-validated through a rigorous programme of pre-testing, field trials and ongoing data capture.

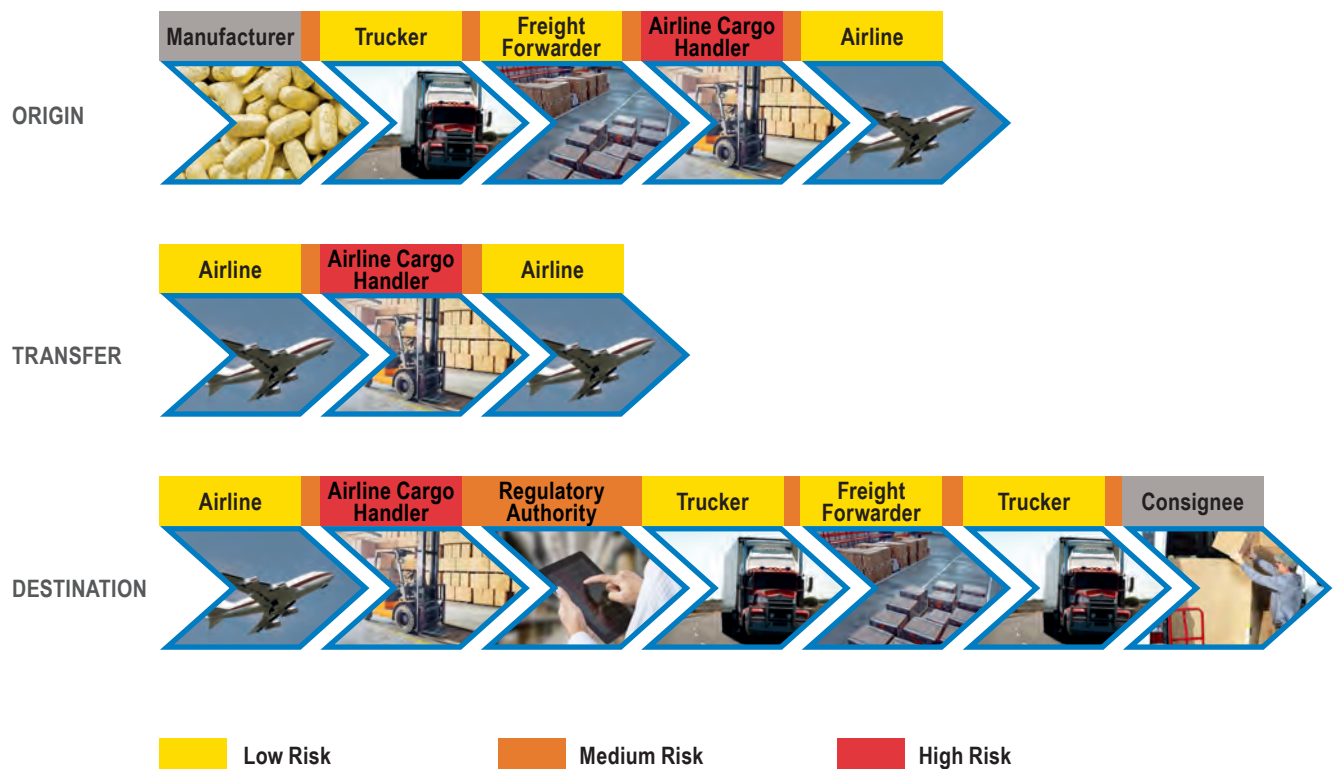
Transportation validation is part of the overall pharmaceutical quality control process. It is essentially a systematic approach to collecting and analysing the necessary data to give reasonable assurance and documented evidence that a specified coolchain system and protocol will consistently operate as expected within specified parameters.

COOLCHAIN ROUTE QUALIFICATION - WHY IT'S NEEDED

Regulatory obligations make it necessary for producers to validate cool chains and qualify their associated shipping

TEMPERATURE EXCURSIONS - WHERE DO THEY OCCUR?

Fig 1



Weak Links

There are a number of recognised weak links in the pharma cool chain (Fig 1). Moving pharma products from A to B has the potential to affect the efficacy and quality of a product or even to render it ineffective or, at worst, dangerous, so it is important that adequate controls are in place to control risk.

Pharma producers bear a heavy responsibility, both legal and moral, to enact and enforce the most appropriate control measures during the shipping stages of the product life cycle. It is a responsibility which cannot simply be abrogated by transferring it along the supply chain and any organisation that neglects product safety is in breach of the law and taking an unacceptable gamble on both its own future and on the safety of the public.

By specifying the service levels required from 3PLs and by participating in key component validations and the development of qualified shipping routes, a pharmaceutical company is able to exercise control of its transport lanes and provide documented evidence that its products are being maintained within acceptable temperature limits throughout their entire journey from factory to pharmacy.

Critical Control Points

In establishing these controls the prevailing laws around GDP provide guidance to pharma companies. However, they are not prescriptive. It is down to the manufacturer, usually in partnership with its logistics partners and component suppliers, to develop and test the appropriate validation measures necessary to prove that their distribution arrangements are under control and 'fit for purpose'. In other words, transport validation has to cover the entire pharma distribution process inclusive of all third party involvements.

This involves establishing the critical control points in the

distribution chain and qualifying each individual step. It is a process that must embrace the entire mix of methods and SOPS relating to personnel, equipment, packaging, transport, storage, measurement, monitoring and recording.

Steps

The individual steps are developed, tested and documented (qualification) followed by testing and documentation of the resulting end-to-end process (validation). The resulting coolchain system with all its component products, processes and procedures must then be actively monitored in use (verification) to ensure it remains relevant to changing operating and environmental conditions.

COOLCHAIN PRODUCT QUALIFICATION

When it comes to the individual components that are used to manage temperature sensitive products in a cool chain, Product Qualification is achieved by subjecting the equipment to two different types of test; fully controlled static tests (Operational Qualification or 'OQ') and dynamic 'in-use' tests (Performance Qualification or 'PQ').

In the case of OQ, this step is conducted under both 'normal' and 'worst-case' environmental conditions to determine the operational parameters of the individual components and to evaluate how they function as part of an overall cool chain system. The overall objective is to control the variations that result from the predictable interplay of all the known coolchain elements in order to ensure pharma product quality and patient safety.

Both OQ and PQ elements of the Product Qualification feed into an overall Transport Validation which, in turn, will typically form part of a manufacturer's overall GDP Process Validation Plan (see Fig 2).



Operational Qualification

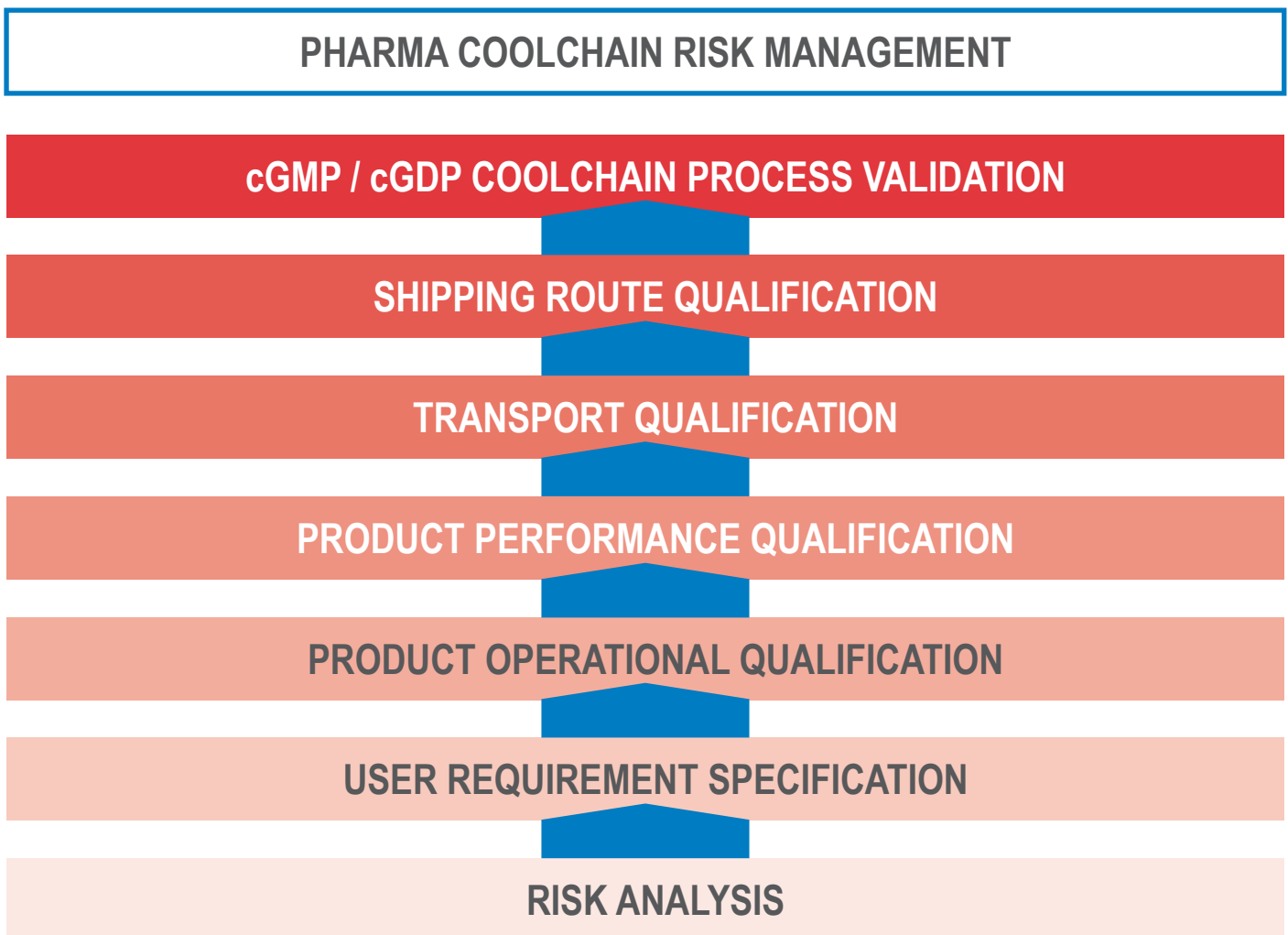
Designed to explore and document the functional envelope for a coolchain component, Operational Qualification (OQ) tests are a vital part of the qualification programme. The OQ tests evaluate the correct functioning of the coolchain components under both the expected and extreme operating conditions that have been identified in a comprehensive GDP risk analysis. Such an analysis includes the identification of hazards and the analysis and evaluation of all risks associated with exposure to those hazards.

This preliminary risk analysis therefore establishes the technical parameters of the component's performance, i.e. its ability to meet or exceed reasonably expected worst-case operating conditions, together with its operating limits. In the case of a coolchain component such as a cargo cover, this preliminary risk analysis must consider all the potential variables at play. For example, with a thermal

cover such as DuPont Tyvek®, the OQ testing needs to consider not only the effects of ambient temperature extremes, but also the importance of solar radiation and its related effects on the potential temperatures experienced by pharma merchandise in transit.

It is essential that this risk analysis is rigorous and thorough because, if and when an unacceptable temperature violation occurs, it will be necessary to demonstrate that the qualification process was appropriate to the risks under consideration.

Fig 2



Pre-Qualification

In some lower-risk cases, OQ tests results may be deemed sufficient to 'pre-qualify' a coolchain component product for 'off-the-shelf' operational use. These 'one-size fit all' solutions reduce costs and save time and for some specific needs can be appropriate. A situation where a pre-qualified coolchain component might be considered appropriate, for example, might involve a regular short-haul route within a single climatic zone using a reliable logistics partner and with a known coolchain infrastructure at journey start and end.

However, a reliance on 'pre-qualified' component products brings its own risks and can lead to protection for temperature-sensitive pharma merchandise that is either under- or over-specified for a given use or situation. Operating conditions can vary enormously even within a given shipping lane. Environmental extremes, different pharma merchandise characteristics and densities, changing loading patterns, varying payload sizes etc. are just some of the factors that can easily lead to 'out of spec' conditions.

Similarly, 'pre-qualified' status is of very little value when it comes to the selection of coolchain components since it confers no recognised standard of quality or performance and there are no normalised test regimes to enable like-for-like comparisons between competing coolchain component products.

Performance Qualification

The Performance Qualification (PQ) determines that both a coolchain component's specified performance and the results from its OQ are achieved consistently when the component forms part of an overall coolchain protocol.

The purpose of the PQ is to verify and document that the coolchain component concerned is functioning correctly and reproducibly within the entire specified working range and limits i.e. its 'fitness for purpose'. Therefore, for PQ purposes the component is always tested as part of an overall coolchain process or process step. This requires the PQ stage to be based around field studies demonstrating how the component performs under actual conditions of use.

However, it must be clear that the PQ part of a transport qualification is designed to demonstrate that the component will function as expected under normal operating conditions. It is not intended as a test against environmental extremes, which by their very nature are unexpected and unpredictable events and consequently cannot be planned for and built-in to this part of the qualification.

Transport GDP Verification - Repeatability and Consistency

Transport verification involves conducting several repetitions of a validated solution to confirm its efficacy in the field. Verification then continues as an ongoing process which is carried out continuously or periodically while the component product remains 'in-service' to ensure that it remains appropriate and effective in use and to accommodate planned and unplanned changes that may have occurred in the distribution chain. In this respect, a clearly defined change control policy must be in place and the principles of corrective and preventive actions (CAPA) applied wherever necessary.

Verification also identifies opportunities for new and upgraded component products and procedures to be introduced. In real-life situations, of course, many of these adjustments



may not become apparent until an acceptable temperature deviation occurs. A system must be in place to ensure that any such excursions are not only recorded but are brought to the attention of the appropriate quality management.

Summary

The latest EU Good Distribution Practice has extended regulatory measures to cover the CRT temperature band and, at a stroke this has substantially increased the volume of pharma products that are now within regulatory scope. Most pharmaceutical merchandise requires storage and transportation at ambient temperature and a failure to take fully validated thermal protection measures could amount to a catastrophic mistake.

So, the burning question is: «Can YOU vouch for the integrity of the key components being used in your coolchain?»



VALIDATION OR QUALIFICATION?

Fig 3

Much confusion surrounds the terms “Qualification” and “Validation” when it comes to good coolchain practice. The terms ‘validation’ and ‘qualification’ are often used interchangeably and both relate, essentially, to the process of proving that a process or equipment is ‘fit for purpose’. Certainly the most important thing of all is to ensure that something is fit for purpose rather than get bogged down in semantics.

However, the International Conference on Harmonisation (ICH) provides the following definitions* which are mirrored in the latest EU GMP guideline**:

Qualification

The action of proving and documenting that equipment or ancillary systems are properly installed, work correctly, and actually lead to the expected results. Qualification is part of validation, but the individual qualification steps alone do not constitute process validation.

Validation

A documented program that provides a high degree of assurance that a specific process, method, or system will consistently produce a result meeting pre-determined acceptance criteria.

What this means in practice is that all components or equipment used in a ‘validated’ coolchain must be individually ‘qualified’. The scope and extent of the necessary qualification steps should be determined using a documented risk-assessment approach.

So a product such as Tyvek® ACC needs to be qualified to show:

1. that it consistently meets its quality and design performance specification - thermal properties, breathability, strength, etc. (Operational Qualification); and
2. that it meets its performance specification under controlled conditions to demonstrate its performance behaviour in the volatility of changeable, real life situations (Performance Qualification).

These component qualification exercises are normally carried out by the product manufacturer i.e. DuPont in the case of Tyvek® air cargo covers. This qualification exercise will normally include an overall analysis of all the relevant elements and procedures of the distribution chain - route, handling, aircraft, airport facilities etc. followed by static ‘worst case’ tests and, lastly, by an empirical ‘in-situ’ service analysis where the outcomes are benchmarked against the static results.

This product qualification then forms part of the overall validation of a shipping route or other coolchain solution. These route validation exercises are normally carried out by the pharma company and/ or its 3PL partners.

*International Conference on Harmonisation (ICH) Good Manufacturing Practice Q7 2000
 **EU Guidelines on Good Distribution Practice of medicinal products for human use (2013/C 343/01)

TYVEK® AIR CARGO COVERS - an Example of a Component Product Qualification Exercise as Part of an Overall Transport Validation Plan

The new generation, Tyvek® Air Cargo covers from DuPont are a typical low-bulk and lightweight passive protection component. Designed to provide cost-effective off-the-shelf CRT protection for pharmaceuticals, these cargo covers employ a unique triple-action approach to temperature control which renders them a very effective and cost-efficient solution to CRT control (see Fig 4).

It is this three-stage protection which differentiates Tyvek® from other cargo covers on the market and DuPont has conducted a number of generic and lane-specific validation exercises to demonstrate their superior performance in the field. Thermal testing of Tyvek® covers is a vital element of the overall qualification process and these tests started with a series of operational qualification (OQ) studies. This involved chamber testing to subject the covers to simulated environmental conditions of a sufficiently extreme nature to demonstrate performance under relatively harsh conditions.

These simulation exercises were then replicated to demonstrate repeatability and consistency and the result was a robust data set which confirmed the expected performance boundaries of the Tyvek® product and provided a benchmark for subsequent validation under dynamic field conditions.

Scope of Programme

The scope of the temperature validation plan was to establish proper distribution and product handling requirements, for the purpose of ensuring the maintenance of appropriate product temperature in transit.

Purpose of Programme

The purpose of the Tyvek® temperature validation plan was to use thermal mapping data to provide documented evidence that a cargo pallet protected with a Tyvek® cover provides robust protection against exterior environmental conditions including exposure to both high and low ambient temperatures and the effects of direct solar radiation.

TYVEK® TRIPLE PROTECTION

Fig 4



- 1 Reflective outer surface minimises solar heat gain
- 2 Low-e metallic surface reduces thermal transfer to cargo
- 3 Microporous structure permits evacuation of excess moisture and condensation

ROUTE PROFILE TEST CONDITIONS

Fig 5



Methodology

The methodology involved assessing the impact of different hazards to enable the degree of risk to be defined. The results were referenced against a selection of contemporary materials currently in widespread use for the passive protection of pharma merchandise.

Tyvek® Operational Qualification

The first part of the temperature validation exercise involved conducting a series of static tests designed to measure the performance of the Tyvek® covers in both summer and winter conditions. The effects of prolonged exposure to the sun were also measured along with the ability of the covers to protect against cold.

The following temperature cycles were conducted:

1. Acclimatise test pallets with load at +4°C for 72 hours. Add covers and expose pallets to sunshine for 48 hours
2. Acclimatise test pallets at 23°C and insert into container at -20°C for 15 hours
3. Acclimatise test pallets at 4°C and insert into container at +20°C for 24 hours
4. Acclimatise test pallets at +20°C and insert into container at 4°C for 24 hours
5. Acclimatise test pallets at +20°C and insert into container at -5°C for 24 hours
6. Acclimatise test pallets at +20°C and insert into container at -0°C for 24 hours

These static tests were a vital part of the qualification programme since they were designed to explore and document the technical characteristics of the Tyvek® product. In other words, they identified the range of operating parameters under which the product will function effectively.

The dynamic tests on the other hand were designed to demonstrate that the Tyvek® component functions as intended under real-life conditions as part of an overall coolchain system. These dynamic tests are not therefore devised in order to prove the operating envelope (although they may serve to do so if 'out of specification' conditions are encountered during the measured validation runs).

Operation Qualification Test Design

The OQ test programme was designed to measure the following material properties:

- Strength/weight
- Water repellency
- Breathability
- Emissivity
- Recyclability
- Conductivity

The OQ test programme was designed to measure the following product properties:

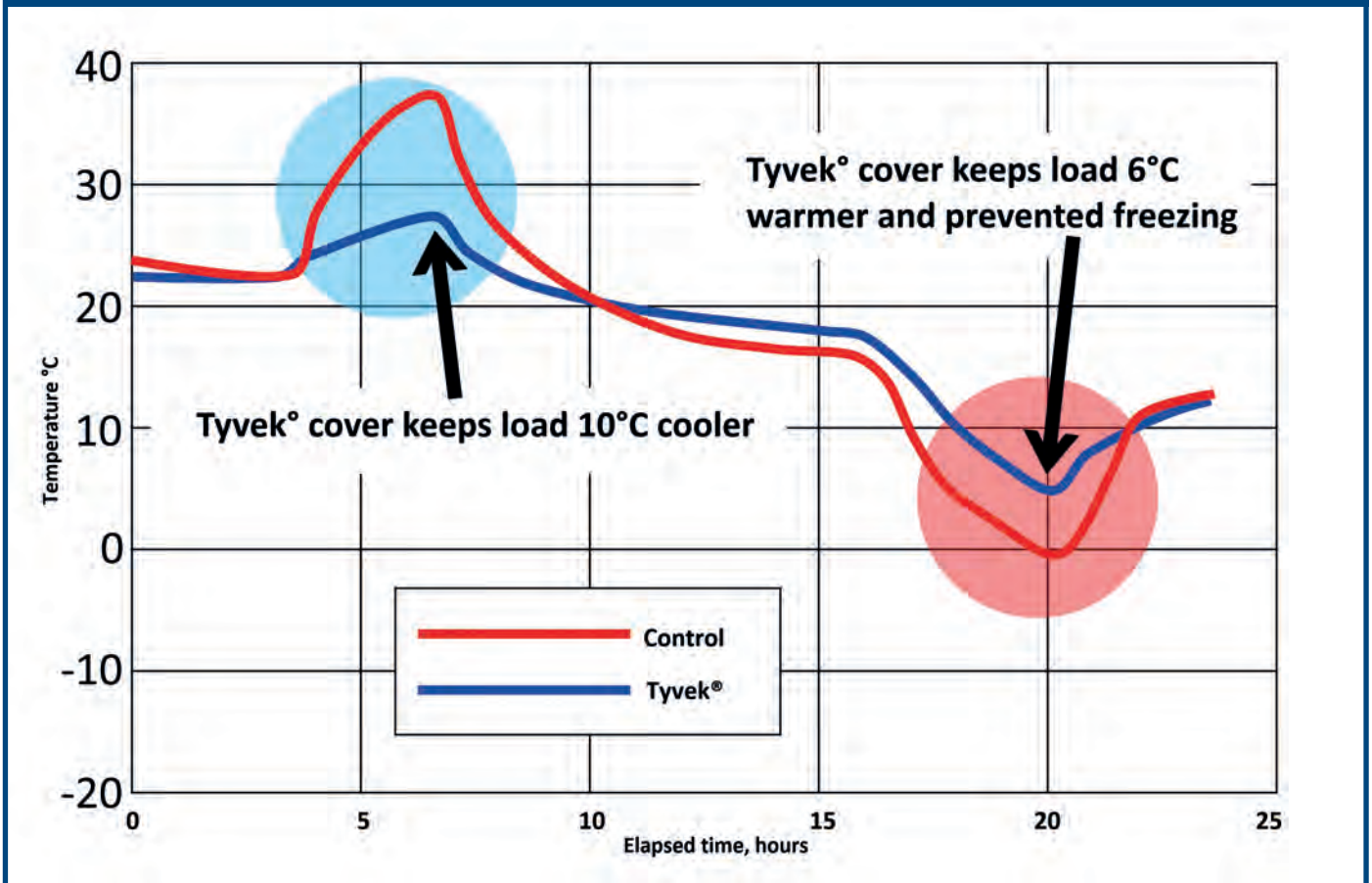
- Thermal performance - ambient temperatures
- Thermal performance - solar radiation exposure
- Thermal properties - cooling characteristics
- Ease of use
- Comparison with competitive alternatives



PROTECTION FROM COLD EXPOSURE

GRAPH SHOWING TOP PRODUCT TEMPERATURE USING TYPICAL ROUTE PROFILE

Fig 6



An example of the route profile test conditions is shown in Fig 5 and an example of the results from these tests in Fig 6.

Solar Radiation Impact

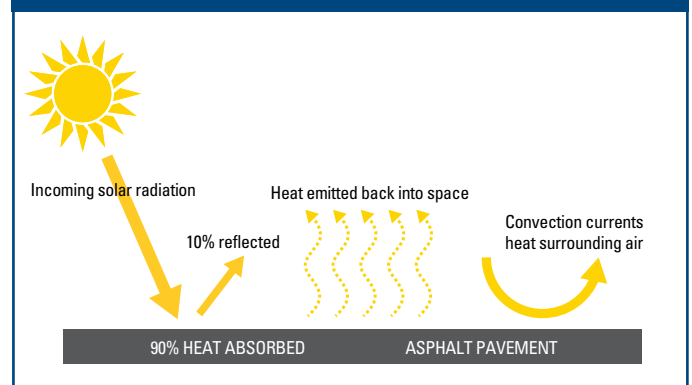
The Tyvek® qualification programme took particular recognition of the effects of solar radiation during the airport apron transfer step since this is widely recognised as the biggest weakness in the pharmaceutical coolchain. During the controlled tests on Tyvek® covers, and in virtually all independent trials, these damaging, but oft-ignored, solar effects were clearly evident.

Direct sunlight can cause exposed surface temperatures to rise as high as 70°C or more and these are temperatures that can be further magnified by local conditions including the 'heat island' effects of solar-heated asphalt pavement (see Fig 7) and the 'mirror' effects of nearby glass and metal clad buildings. According to IATA, 57% of temperature excursions occur

during these 'uncontrolled' air-cargo stages of the distribution process. During such intervals, pharma merchandise can be exposed to exceptional temperature extremes as a result of the 'greenhouse' effect of solar radiation, the very same heating phenomenon associated with global warming. And the resulting temperature excursions are not rare

AIRPORT APRON 'HEAT ISLAND' EFFECT

Fig 7



occurrences. It has been estimated by one authoritative source that up to 5% of all transport events involve a temperature deviation from plan with external air handling operations, such as loading, unloading, marshalling and transfer, accounting for a high proportion of the temperature spikes encountered during the transportation of drugs.

In the past, many pre-qualification tests for cargo covers ignored this important phenomenon and relied solely on temperature profiles based on ambient temperatures when conducting risk analyses and undertaking performance tests. However, it is clear that, in practice, exposure to direct sunlight is a very common and very serious cause of temperature excursions and must be addressed accordingly.

The Danger of Stretchwrap

Initial trials on Tyvek® covers in India had shown temperature differences of as much as 25°C between standard stretch-wrapped pallets and identical pallets cloaked with Tyvek® covers when both were subjected to solar radiation over a 3-day period. Similar measurements were subsequently repeated in many other geographical zones in Europe, Asia and the Americas.

In another Tyvek® qualification test, four pallets of pharma products, two using Tyvek® covers and the other two covered with standard plastic stretchwrap, were temperature-monitored throughout a six and a half day door-to-door shipment from Brazil to France. This journey involved wide ambient temperature fluctuations from as low as 5°C to a peak of nearly 40°C.

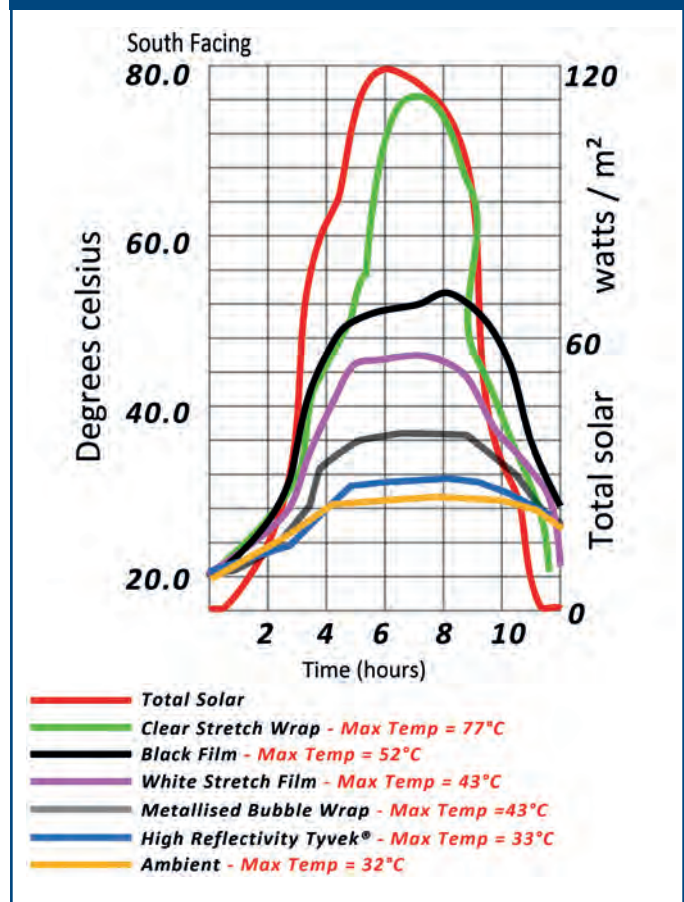
In this particular test the Tyvek® pallets remained within the desired 15°C temperature envelope throughout the test whilst, in contrast, both the stretch-wrapped pallets rapidly breached the predetermined temperature band. In fact some temperature sensors positioned within the stretchwrap pallets indicated, alarmingly, 'out of limit' temperatures for periods exceeding 24 hours.

Greenhouse Effects

The static OQ trials compared the use of clear and black cargo coverings with Tyvek® to determine their relative behaviour under identical environmental stimuli. The results were striking. Transparent cover materials were found to exhibit

SOLAR RADIATION EFFECTS WITH DIFFERENT COVER MATERIALS

Fig 8



an alarming degree of heat entrapment and magnification, the so-called 'greenhouse effect', as the sun's rays were captured and trapped. Common packaging materials such as stretchwrap and bubblewrap did not provide any protection against solar radiation, but rather amplified its warming effects way beyond the surrounding "ambient" air temperature, and often to a potentially dangerous degree.

Similarly, black and coloured materials gained heat energy by absorbing the sun's rays and increased the surface temperature of the 'protected' packages way beyond the surrounding "ambient" air temperature (see Fig 8.) The Tyvek® air cargo covers, on the other hand, were found to sharply restrict this solar heat gain due to their exceptional reflective properties in both the visible and infrared radiation wavelengths.

Yet more OQ tests were conducted at the Atlas Weatherisation Test Facility in Florida during punishing ambient conditions in March 2013. This part of the programme also involved comparative tests against alternative cover materials and

systems and again demonstrated the striking superiority of the Tyvek® covers especially under exposed, high solar-gain, 'tarmac' conditions. Again, these tests showed that standard clear and black stretch-wraps, although cheap and widely used, tend to act like a greenhouse by trapping heat and continuously increasing the entrapped air temperature way beyond the surrounding ambient temperature.

Tyvek® Performance Qualification

The Performance Qualification part of the validation exercise involved a dynamic transport test measuring representative pallets of material during conveyance over a demanding return freight route involving a number of steps and a range of typical, but not extreme, environmental stresses. The route chosen and its various phases are shown in the illustration (Fig 8).

Decisions that had to be made when selecting the route included the length and duration of the route together with the coolchain facilities, the number of transit steps, the logistics suppliers, the mode of flight, the shipping and airport coolchain facilities, the potential impact of delays and the anticipated weather conditions.

Performance Measurement

The decision as to what needed to be measured, and how, were fundamentals of the validation design. Three dataloggers per pallet were placed inside carton boxes and a further datalogger was placed on top of the cargo outside the cover to measure external temperature.

Purpose of performance qualification

It is important to note that the purpose of the Tyvek® PQ was to demonstrate that the Operational Qualification results were applicable to real-life conditions and that the measured performance patterns were mirrored in the field. The PQ was not, per se, an exercise to demonstrate the technical performance capabilities of the product under extreme or unexpected conditions. It is not realistic from a practical or economic perspective to attempt to run sufficient performance qualification runs to experience and measure random temperature extremes.

Fig 9 shows the designated pallet configuration and the location of the thermal sensors in the corners of the pallet, regarded as the most sensitive place to temperature excursions during shipment. The sensors used were calibrated model EBI 300 / EBI 310 loggers from EBRO.

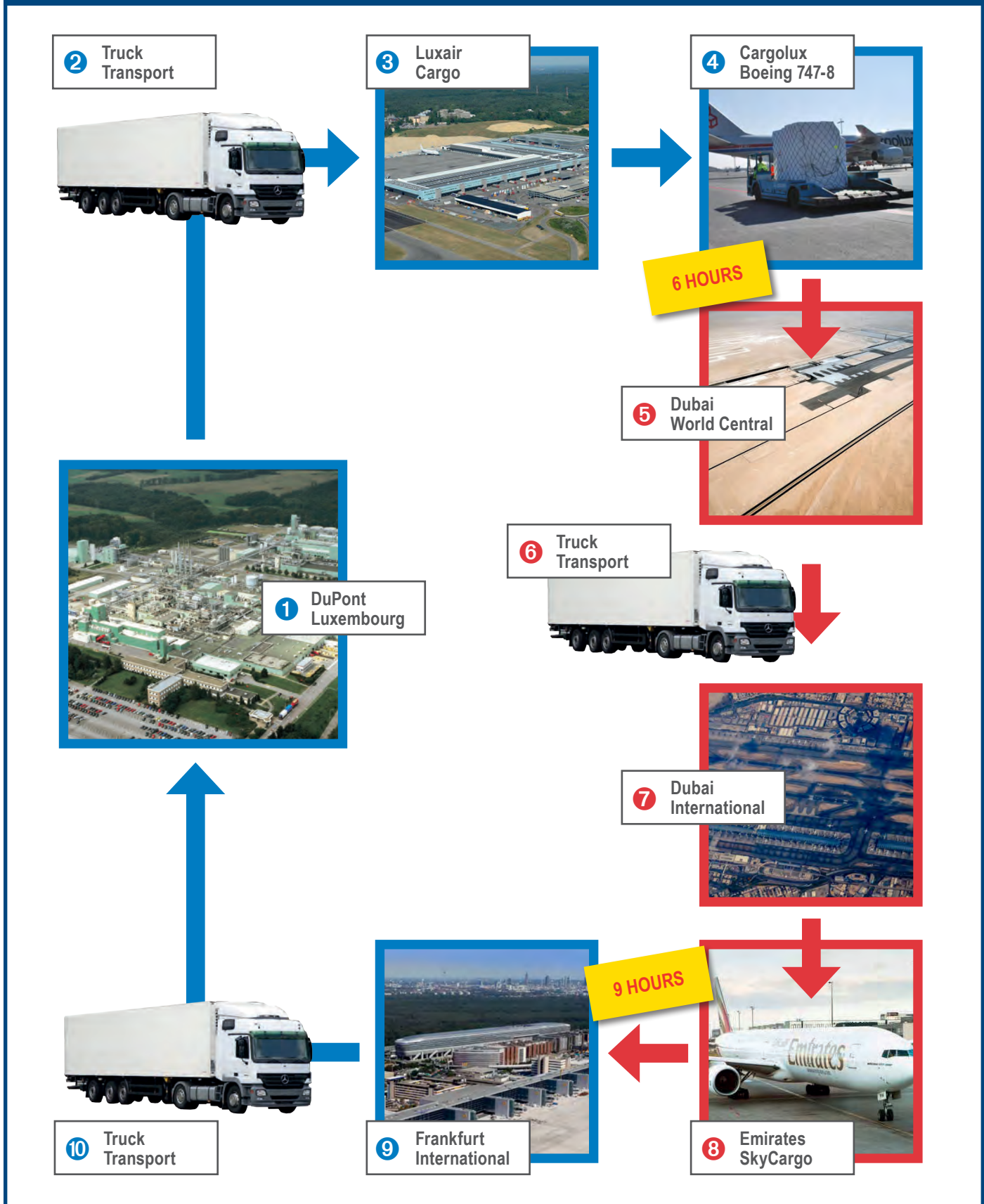
The test was conducted with standard Euro pallets loaded with a total of 32 boxes in 4 layers. The boxes were made of double-walled corrugated board and each of these contained three 1.5 litre plastic bottles of water representing a typical medium mass pharma product. The air/water ratio of each pallet was approximately 80%. The pallet was consolidated on the pallet with standard plastic strapping.

Two versions of Tyvek® were tested. One of these was the standard (uncoated) 'WW' Tyvek® cover, normally used for the protection of perishable foods and flowers. The other was the internally silver-coated Tyvek® 'WS' version, normally used for high-value pharmaceutical products. A control pallet of identical size and content was included and this was covered with a clear stretchwrap film.

The test run was designed to illustrate the performance of the covers as part of a coolchain system under typical real-life conditions. In this case there were no out-of-the-ordinary extremes of temperature, there were no undue tarmac delays and there was little exposure to solar radiation. Nonetheless, the PQ was an unqualified success. The Tyvek® covers performed exactly as expected and demonstrated a consistent and significant improvement over conventional wrapping materials.

PERFORMANCE QUALIFICATION - TRANSPORT VALIDATION RUN

Fig 9



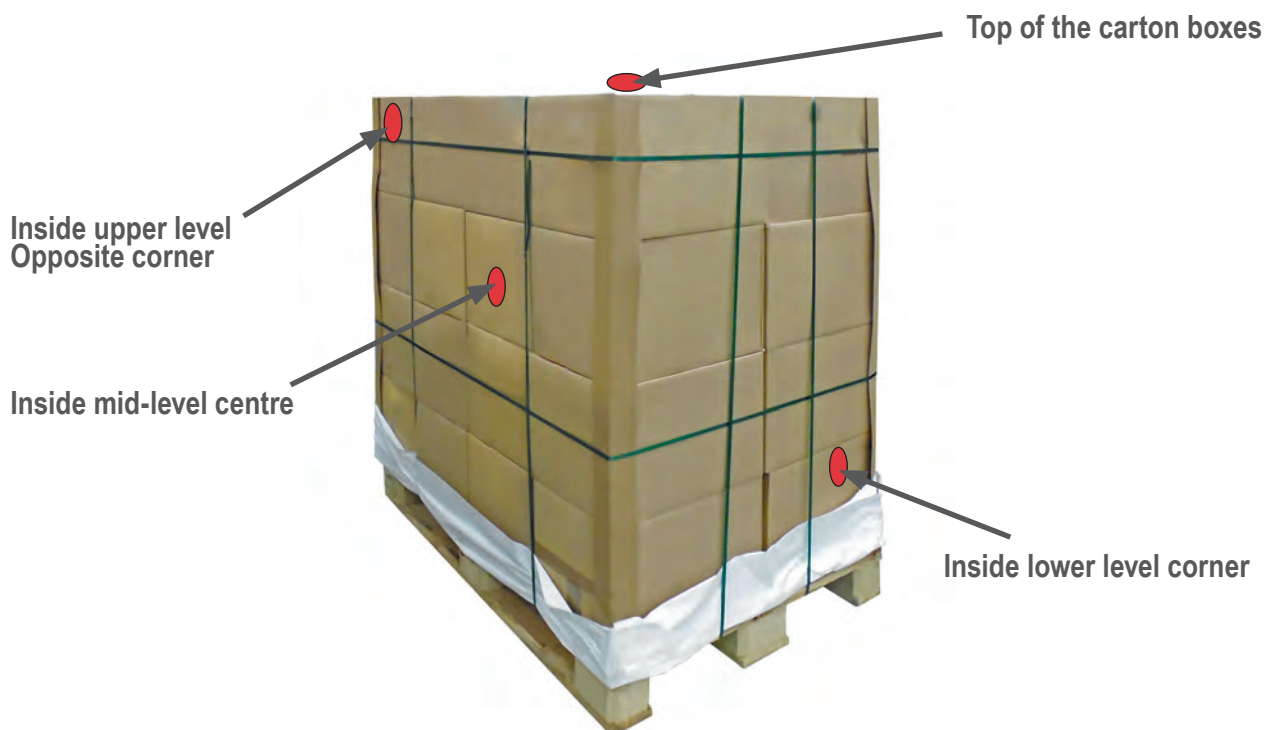
ARE YOUR COOLCHAIN SOLUTIONS VALIDATED?

The results of this first phase of the Tyvek® qualification exercise were unequivocal and proved conclusively that when used in accordance with the manufacturer's instructions, Tyvek® air cargo covers provide a significant improvement in product temperature stability and can be used with confidence to meet current regulatory requirements.

The qualification also demonstrated the technical superiority of the Tyvek® cover compared to alternatives in common use.

PALLET BUILD AND SENSOR POSITIONNING

Fig 6



Euro Pallet 80 x 120 cm, 120 cm high
Carton boxes: 29 cm x 39 cm x 29 cm high



ABOUT THE AUTHOR AND DUPONT PROTECTION TECHNOLOGIES

Malik Zeniti was Manager of Business Development at DuPont Protection Technologies (DPT) in Luxembourg, focused on the market development and sales of the thermal air cargo covers business branded Tyvek® in EMEA.

He is also an active Member of the Cool Chain Association.

We have published this white paper to help pharmaceutical quality, safety and logistics executives understand some of the issues surrounding the successful qualification of thermal cargo covers for air freight applications.

If you have any comments or would like to find out more about coolchain management and thermal control please feel free to contact:

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