

TYVEK® CARGO COVERS: PHARMACEUTICAL TECHNICAL STUDY

Controlled Room Temperature (CRT) Product Protection

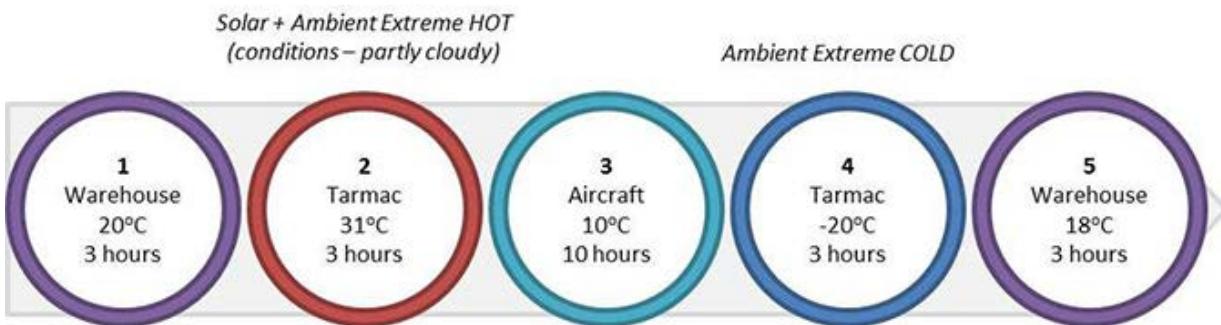
PURPOSE:

Evaluate the performance of Tyvek® Cargo Cover to protect simulated Controlled Room Temperature pharmaceutical product through a simulated route in which the product is exposed to solar radiation and both hot and cold ambient extremes.

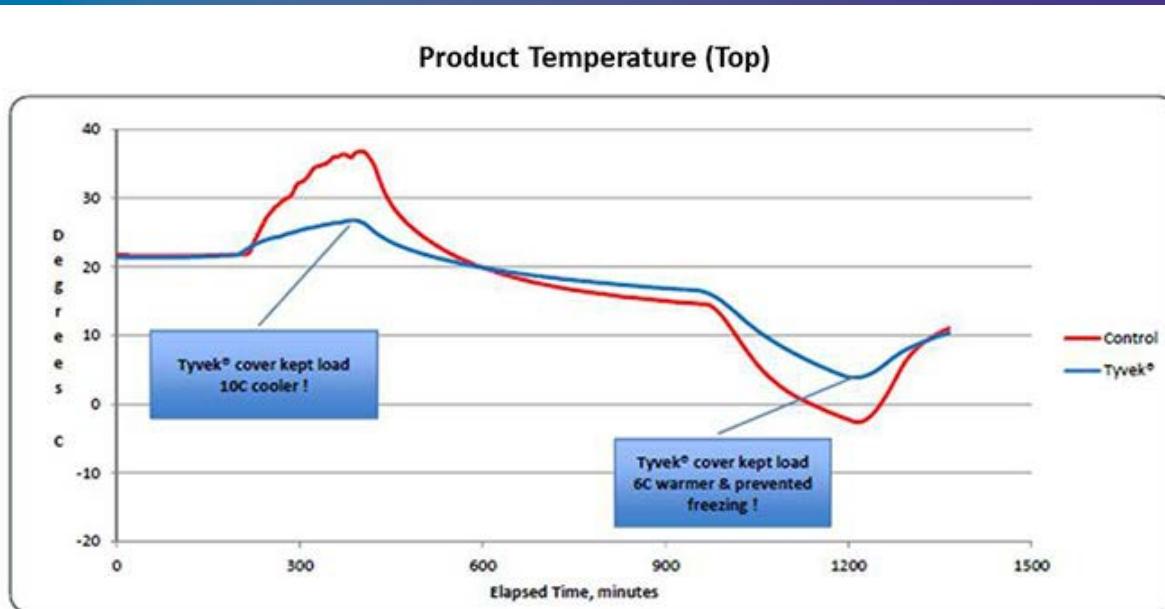
METHOD

- Test sample – Euro sized pallet protected with a low emissivity Tyvek® Cargo Cover
- Control sample – Euro sized pallet with no protection, current case
- Pallet configuration – 18 boxes (15" x 15" x 15") stacked 3W x 2D x 3H
- Low-to-medium thermal mass (110 liters water, liqui-packs). Simulated product – saline-filled vials.
- Temperature probes inserted into vials.
- 7 data loggers (21 temperature probes) were installed per pallet at typical excursion spots.

Route Profile

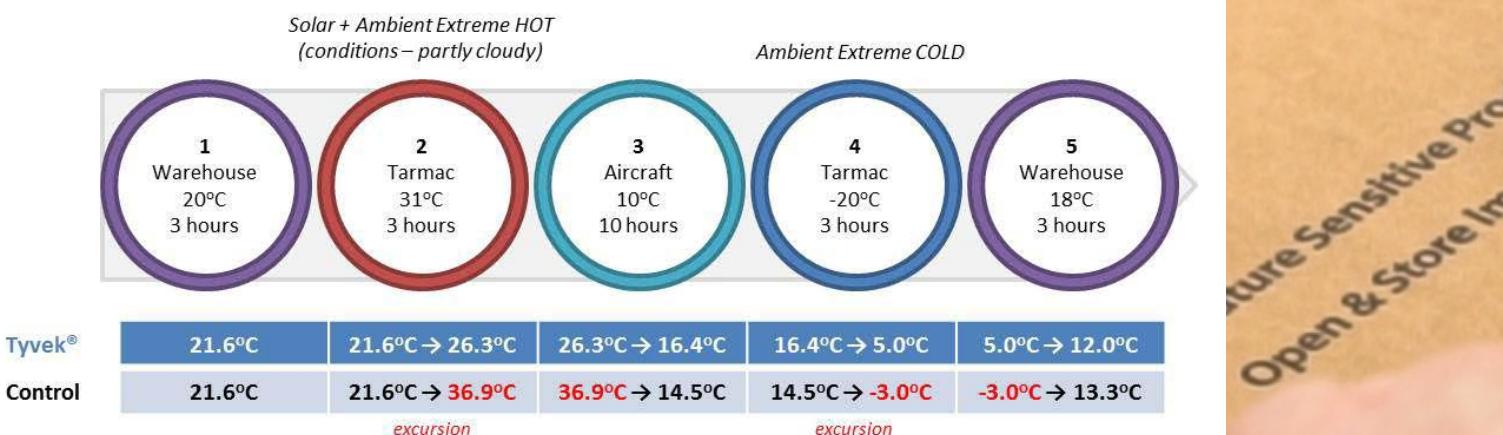


Route Profile - Simulated actual pharmaceutical route, leaving northern hemisphere in summer with solar radiation and hot ambient extreme exposure, landing in southern hemisphere in winter with cold ambient extreme exposure.



Test Data: Product Temperature (Top)

Starting & Ending Product Temperatures (Top)



Starting & Ending Product Temperature (Top) - Excursions shown in red text.

TEST DATA:

Please see test data graph above.

RESULT:

- Zero temperature excursions with Tyvek® vs Two excursions for Control sample
- 10°C (18°F) reduction in peak temperatures on tarmac in summer conditions vs control
- 6°C (11°F) improvement in peak temperatures on tarmac in winter conditions vs control
- Tyvek® Cargo Cover moderates rate of heating and cooling of product vs control

BENEFITS DEMONSTRATED:

- No excursions despite 3 hour exposures to solar radiation + hot and cold ambient extremes
- Tyvek® Cargo Cover prevented the product from freezing (while control did not)

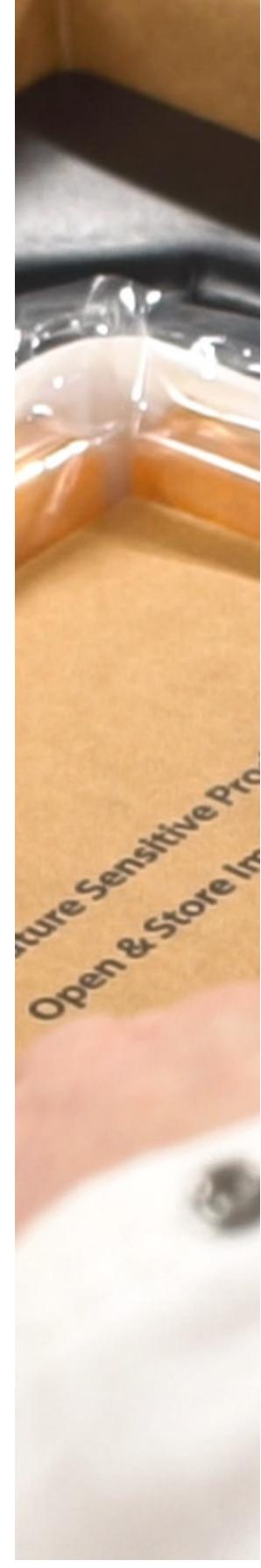
Tyvek® Cargo Covers provide excellent "all-in-one" protection from solar radiation AND ambient extremes (hot and cold), helping you conserve your stability budget.

All technical information set out herein is provided free of charge and is based on technical data believed to be reliable. It is intended for use by persons having skill, at their own discretion and risk. The handling precaution information contained herein is given with the understanding that those using it will satisfy themselves that their particular conditions of use present no health or safety hazards.

Since conditions of product use are outside of our control we make no warranties express or implied in relation thereto and therefore cannot accept any liability in connection with any use of this information. Nothing herein is to be taken as a license to operate under, or a recommendation to infringe any patents.

To maintain efficacy, DuPont™ Tyvek® Cargo Covers must be stored in the original package under dry, normal temperature conditions. DuPont™ Tyvek® Cargo Covers have been designed for one-time or limited use in line with sanitary regulations and pest management best practices. Sufficient pre-cooling and correct temperature management from start of the cool chain is essential for optimal performance. DuPont is not liable for product damage during the use of the cover. Cold Chain Technologies, LLC is not liable for product damage during the use of the cover.

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