



PUFFIN PACKAGING™
planet friendly packaging

WoolPac Mailing Bags for Cold Chain Pharmaceutical Shipments: Solutions for Hotter Summer Conditions

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1. Summary

Following testing conducted to evaluate the performance of revised insulated packaging solutions for single item pharmaceutical product shipments, further testing was conducted to demonstrate the suitability of packaging for hotter temperatures observed during periods of the summer in the UK; revised recommendations are provided for the packing configurations used, such as the quantity of ice packs used.

2. Testing Procedure

2.1 Testing Methods

Testing was conducted at Puffin Packaging in temperature-controlled test chambers, following its in-house standardised testing procedures, a method based on the ASTM Standard D3103-22 “Standard Test Method for Thermal Insulation Performance of Distribution Packages” and ISO 22982-2:2021 “Transport Packaging — Temperature controlled transport packages for parcel shipping”.

The packages were tested against a temperature profile which simulates temperatures typically observed during UK mainland courier transport. Tests were terminated after 48 hours, or at the point of failure of all test specimens; failure was determined by breach of cold chain boundaries (+2 to +8°C).

All tests were conducted in an equal and unbiased method to determine the most suitable packaging solution.

2.2 Temperature Profiles

Temperature profiles were developed using data collected by sending dataloggers via courier between locations in the North and South of England every week to measure conditions during transit. The hotter summer conditions were only observed on a limited number of days during the year.

“Heatwave” Summer Profile

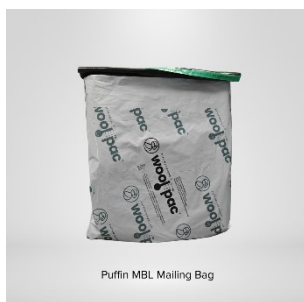
Time	Time (Hrs)	Temperature (°C)	Accumulative Time (Hrs)
8am-11am	3	20	3
11am-2pm	3	24	6
2pm-4pm	2	30	8
4pm-6pm	2	24	10
6pm-12am	6	19	16
12am-8am	8	17	24

2.3 Datalogging

Elpro Libero CL Dataloggers (ISO 17025 calibrated, and 21 CFR part 11 compliant) were placed in the primary packaging to measure internal temperatures, and three dataloggers were placed within the testing chamber were used to measure the external (chamber) temperature.

Temperatures were recorded in 10-minute intervals. Results were compiled to produce the graphs shown in the “3.0 Results” section.

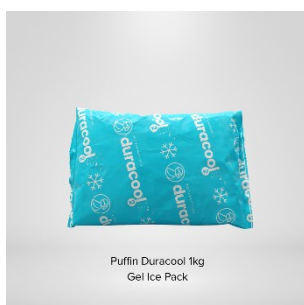
2.4 Materials used



Puffin MBL Mailing Bag

Insulated Packaging

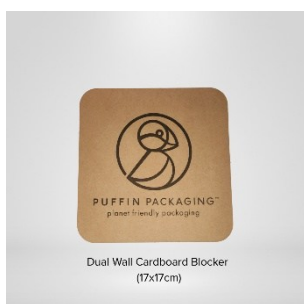
WoolPac mailing bags comprise wool nonwoven pad sealed in MDPE film and fitted into an outer MDPE bag. Puffin's recently revised WoolPac liner was used during this test; revisions were made to reduce materials while providing the same or better performance. Packed mailing bags were placed in an outer crash lock box alongside a sharps bin (20.5 x 7 x 12 cm).


Puffin Duracool 1kg
Gel Ice Pack

Phase Change Materials

Duracool gel ice packs were used in all tests conducted. Ice packs were frozen at -21°C for a minimum of 48 hours prior to testing, and conditioned for approximately 40 minutes at 20°C to remove sensible heat to prevent "cold shock" to products –residual sensible heat from the freezer causing the product to breach cold chain temperatures.

For "heatwave" configurations, 1kg, 500g and 270g gel ice packs were used. Puffin currently offer 1kg, 560g and 270g Duracool, however bespoke sizes can be requested (subject to volume).


Dual Wall Cardboard Blocker
(17x17cm)

Blockers

As outlined in the Rules and Guidance for Pharmaceutical Distributions (The MHRA Green Guide) 2022, a divider is required to separate the product from phase change materials to prevent a breach of cold chain boundaries (+2 to +8°C). A 17 x 17 cm dual wall corrugated cardboard blocker was utilised.



Mounjaro KwikPen

Payload

To simulate payload, an empty Mounjaro Kwikpen, leaflet and primary packaging (17 x 5.5 x 4 cm) were used. The datalogger to measure payload temperature was inserted into the product box alongside the pen and leaflet. The payload was stored in a 5°C refrigerator for a minimum of 24 hours prior to testing.

2.5 Packing Configurations

Packing Protocol

Ice packs were frozen for >48 hours prior to testing. Prior to packing, the ice packs were conditioned at room temperature and added to the mailing bag (MBL). The product box was inserted in the MBL with a blocker separating the product from the ice packs. The liner in the MBL was closed over the product and ice pack, and the mailing bag was sealed tightly, ensuring that the insulation was fully covering its contents. The MBL was placed in the crash lock box along with a sharps bin, before the box was sealed completely. The boxes were placed on wire rack shelves in the test chamber, and loggers measuring the external temperature were added to upper, mid and lower locations within the chamber.

“Heatwave” Summer Configurations

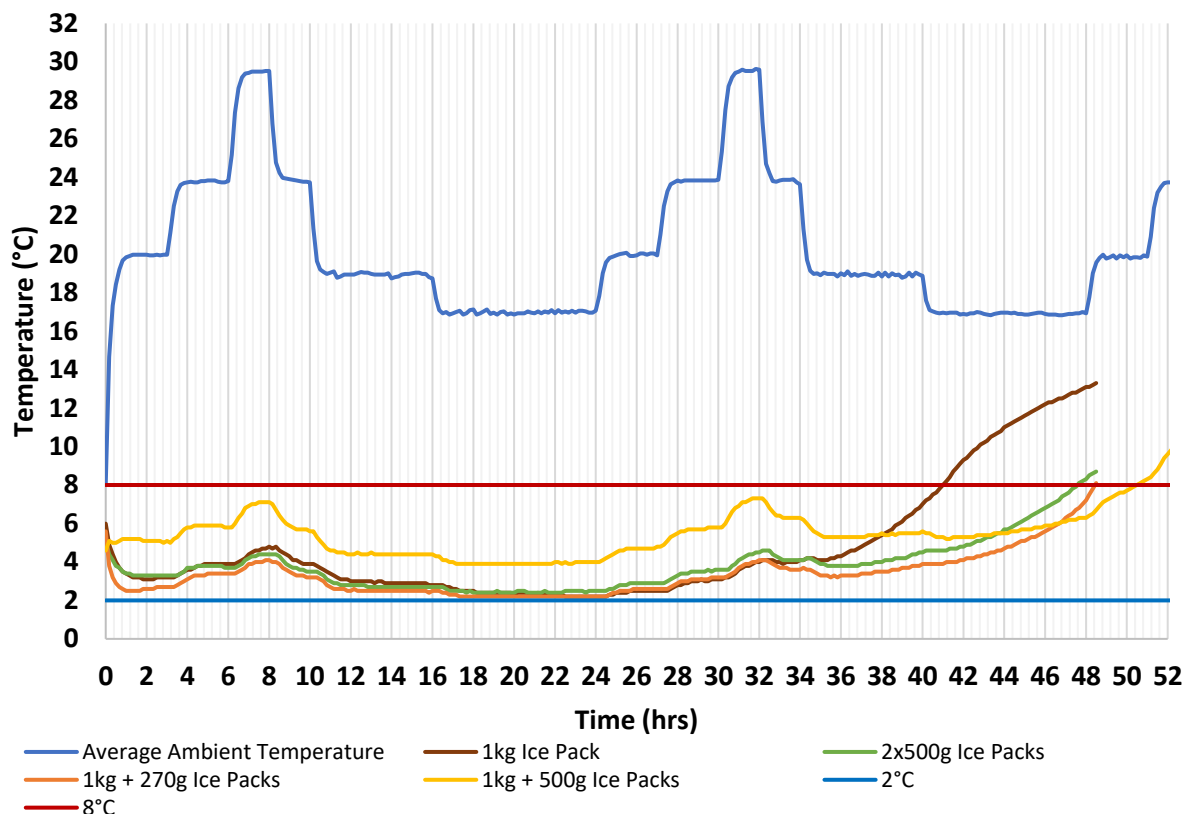
The following configurations were tested against the summer profile:

1. Revised WoolPac MBL with 1x1kg Duracool ice pack
2. Revised WoolPac MBL with 2x500g ice packs on one side
3. Revised WoolPac MBL with 1x1kg and 1x270g Duracool ice packs on one side
4. Revised WoolPac MBL with 1x1kg Duracool and 1x500g ice pack on one side

3. Results

A summary of the test conducted is described below, the key results/findings are detailed in bullet points.

Summer Profile



- The results displayed in the graph show optimal configurations of ice packs used in a WoolPac MBL. All configurations used ice packs packed on one side of the mailing bag; placing ice either side of the payload is likely to result in payload temperature dropping below the 2°C lower cold chain limit.
- A single 1kg Duracool gel ice pack was capable at maintaining a payload temperature within cold chain limits for up to 41.2 hours; this solution is the simplest in terms of packing configuration and utilises the same recommended packing configuration as previously proposed for summer and mid-season temperatures.
- However, in this packing configuration and size of mailing bag, the use of two 500g ice packs proved more effective than one 1kg ice pack, increasing the duration within cold chain limits to 47.7 hours.
- Exceeding 48 hours was possible by increasing the amount of ice used, adding a second ice pack to an MBL containing a 1kg Duracool. While a combination of a 1kg and 500g ice pack was most effective, achieving 50.7 hours below 8°C, the space inside the mailing bag was constrained, and may hinder packing. The combination of a 1kg and 270g Duracool provides better fitment, and in testing achieved 48.5 hours.

The packing configuration recommended based on results and preparation of packages for testing is:

For 36+ hours: Revised WoolPac MBL with a 1kg Duracool (or equivalent) ice pack.

For 48+ hours: Revised WoolPac MBL with a 1kg and 270g Duracool (or equivalent) ice pack.

4. Conclusion

Revised Puffin WoolPac mailing bags were tested against a “heatwave profile” to determine an optimal solution for hotter summer conditions, utilising different configurations and quantities of ice packs to maintain payload temperature within cold chain limits for 48+ hours.

The following packing configurations were tested and recommended:

Solution	Packing Configuration	Performance (+2°C to +8°C)
1x1kg Duracool	Revised WoolPac MBL with a 1kg Duracool (or equivalent) ice pack.	41.2 hours
2x500g Ice Pack	Revised WoolPac MBL with 2x500g Duracool (or equivalent) ice pack.	47.7 hours
1x1kg and 1x270g Duracool	Revised WoolPac MBL with a 1kg and 270g Duracool (or equivalent) ice pack.	48.5 hours
1x1kg Duracool and 1x500g Ice Pack	Revised WoolPac MBL with a 1kg and 500g Duracool (or equivalent) ice pack.	50.7 hours

The simplest solution, a 1kg ice pack, and solution proposed for all seasons other than winter provided 41 hours of performance, while increasing the volume of ice extended performance over 48 hours, but sacrificed ease of packing.

Two 500g ice packs proved to be more effective than a single 1kg ice pack in this scenario, likely due to optimal shape for packing.

The recommended solutions above provide the best performance using Puffin Packaging’s current products. There is scope for testing and the supply of bespoke ice packs if required; this could potentially improve performance and/or packing fitment.

This report was produced to demonstrate the performance of packaging after revisions being made to the product, as well as recommended packing configurations to suit hotter UK weather conditions. As Puffin Packaging cannot validate products, testing should also be conducted by the distributor to ensure the product meets requirements for their specific use case. Samples can be provided on request for your own independent testing.