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Design Qualification Report for the MaxPlus PharmaPack (4L, 48+ hour solution)

Intended for refrigerated (2-8°C) transport of specialty pharmacy products



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1. Scope:

The scope of this Design Qualification (DQ) report is to summarize the components and thermal performance of the MaxPlus PharmaPack SP Shipper (SKU# 1RPPV48-4). The report addresses shipper specifications, components breakdown, packing methods, and temperature compliance data to transport refrigerated specialty pharma products at 2-8°C for a minimum of 48 hours.

2. Shipper Specifications:

- Outer Shell Material: Corrugated Cardboard
- Outer Dimensions: 11.25in x 9.25in x 9.25in (LWH)
- Payload Dimensions: 10in x 8in x 3in (LWH)
- System Weight (excluding payload): 11.6 lbs.
- Phase Change Coolant:
 - NI-W8L9 (x2) (7.5" x 8.5" x 1")



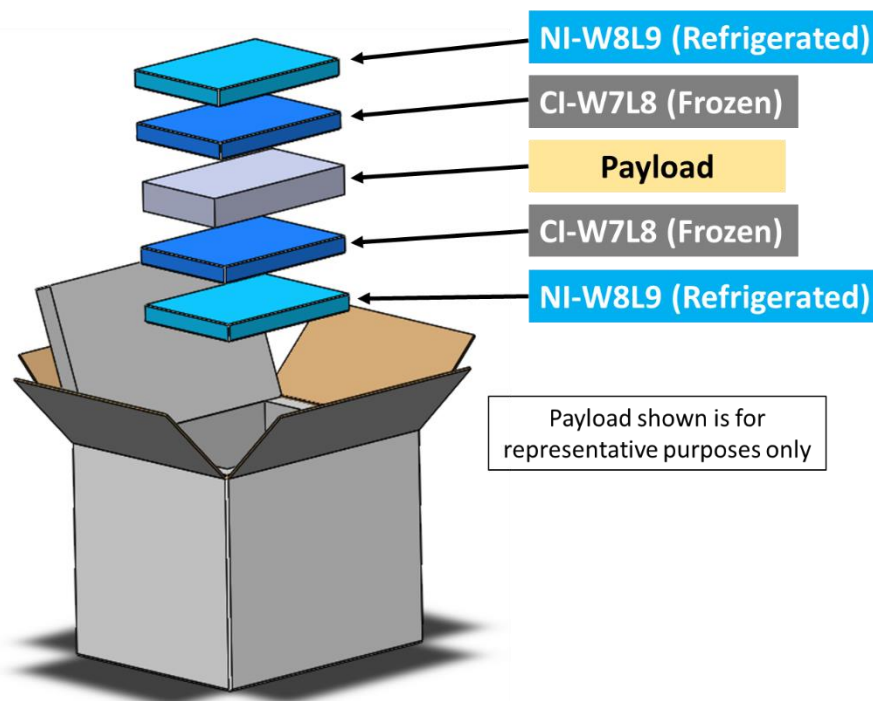
- CI-W7L8 (x2) (7" x 8" x 1")



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3. Packing Methods

3.1 Packout Schematic (Winter):



3.1.1 Winter Coolant Conditioning Procedure:

- 2 x Coolant NI-W8L9 (**White brick with Blue marking – Nordic Ice**) stored in the refrigerator (between 2°C to 8°C) for a minimum of 24 hours
- 2 x Coolant CI-W7L8 (**White PCM Pouch**) stored in freezer (below -10°C) for a minimum of 24 hours

To pack the shipper, take out frozen coolants from the freezer and condition them laying flat on a benchtop for 30 minutes at room temperature.

Note: Make sure that the frozen pouches are frozen solid before removing them from the freezer. Don't stack the pouches on top of each other on the benchtop.

3.1.2 Packing Instructions (Winter):

Step 1: Open the lid of the flexible insulation and insert one **refrigerated Coolant NI-W8L9** brick (white/blue) into the shipper.

Step 2: Insert one **frozen Coolant CI-W7L8** pouch (white) on top of the refrigerated Coolant NI-W8L9.

Step 3: Insert the **payload** on top of the frozen Coolant CI-W7L8 pouch.

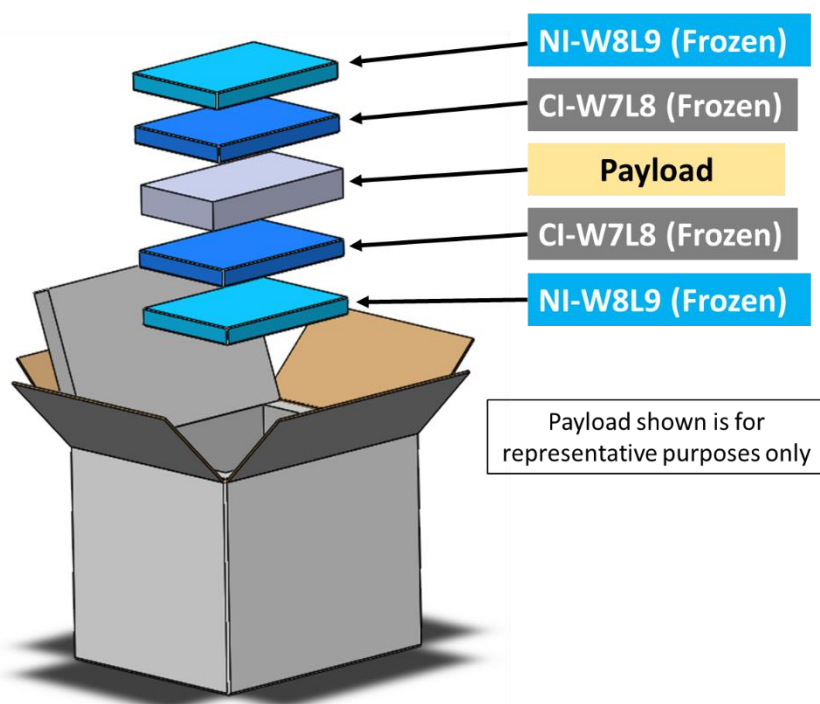
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Step 4: Insert the second **frozen Coolant CI-W7L8** pouch (white) on top of the payload.

Step 5: Place the last **refrigerated Coolant NI-W8L9** pouch (white/blue) on top of the second frozen Coolant CI-W7L8 pouch.

Step 6: Close the lid and use packaging tape to seal the box.

3.2 Packout Schematic (Summer):



3.2.1 Summer Coolant Conditioning Procedure:

- 2 x Coolant NI-W8L9 (**White brick with Blue marking – Nordic Ice**) stored in the freezer (below -10°C) for a minimum of 24 hours
- 2 x Coolant CI-W7L8 (**White PCM Pouch**) stored in the freezer (below -10°C) for a minimum of 24 hours

To pack the shipper, take out all frozen coolants from the freezer and condition them laying flat on a benchtop for 30 minutes at room temperature.

Note: Make sure that the frozen pouches and bricks are frozen solid before removing them from the freezer. Don't stack the pouches on top of each other on the benchtop.

3.2.2 Packing Instructions (Summer):

Step 1: Open the lid of the flexible insulation and insert one **frozen Coolant NI-W8L9** brick (white/blue) into the shipper.

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Step 2: Insert one **frozen Coolant CI-W7L8** pouch (white) on top of the frozen coolant NI-W8L9.

Step 3: Insert the **payload** on top of the frozen coolant CI-W7L8 pouch.

Step 4: Insert the second **frozen Coolant CI-W7L8** pouch (white) on top of the payload.

Step 5: Place the last **frozen Coolant NI-W8L9** brick (white/blue) on top of the second frozen coolant **CI-W7L8**.

Step 6: Close the lid and use packaging tape to seal the box.

4. Design Qualification Test Methods and Results:

5.1 Test Methods: The presented 1RPPV48-4 PharmaPack SP Shipper with 4 x PCM pouches is designed to maintain product between 2-8°C for a minimum of 48 hours. 2 different test cases were conducted to demonstrate the shipper's ability to meet the ambient requirements. Thermal chambers with NIST traceable calibration were programmed with a summer and winter ISTA-7D ambient profiles for testing. Data logger (NIST traceable calibration) with probes were taped to the payload simulant units to measure payload temperature during test runs. The shippers were prepared and packed following the methods listed in Section 3 and placed inside a thermal chamber for 48 hours. At the end of the test run, payload temperature data was downloaded and analyzed to assess the systems' performance.

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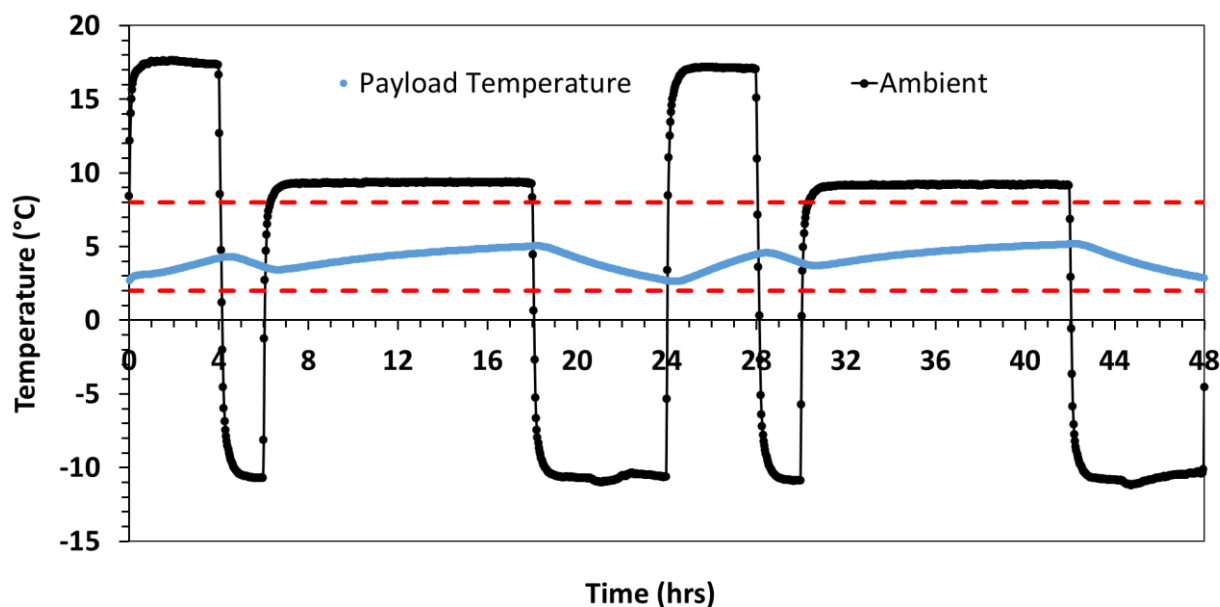
4.2 Test Results:

4.2.1 Payload maintained at 2-8°C | Winter Ambient

Test setup:

Test payload	2 x 60mL water pouches kept at 2°C to 8°C for 24 hours
Ambient temperature	Winter Ambient
Test duration	48 hours

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

Total time (hours) payload-maintained 2 – 8°C	Minimum payload temperature reached during tested duration
48	2.6°C @ 24.5 hours

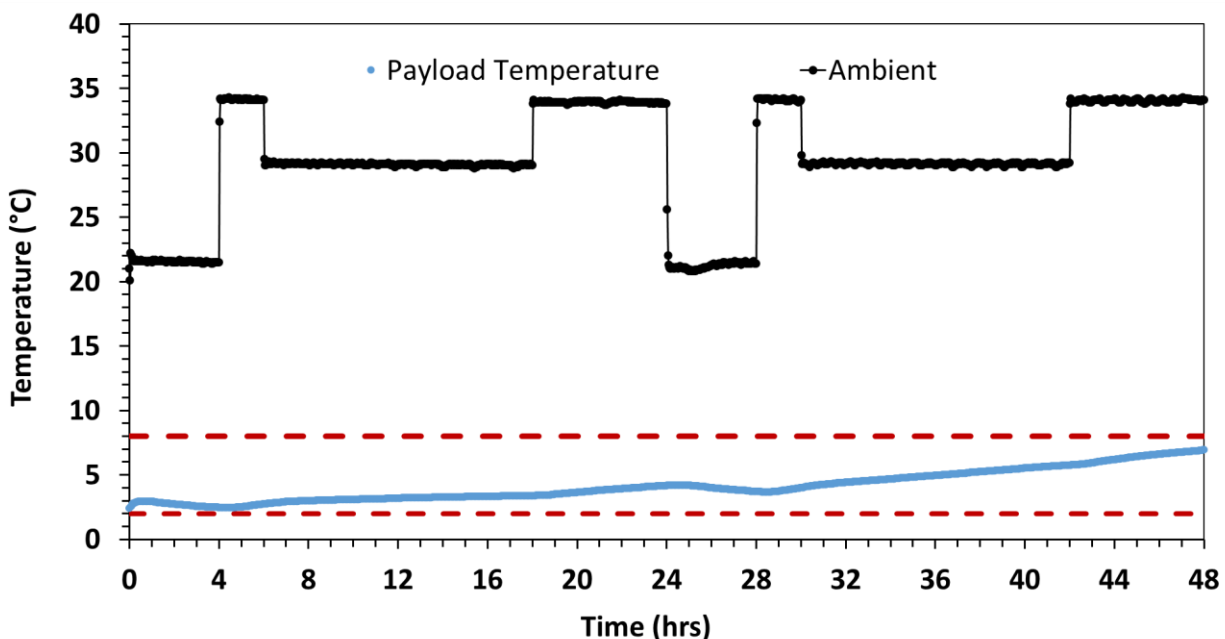
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4.2.2 Payload maintained at 2-8°C | **Summer Ambient**

Test setup:

Test payload	2 x 60mL water pouches kept at 2°C to 8°C for 24 hours
Ambient temperature	Summer Ambient
Test duration	48 hours

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

Total time (hours) payload-maintained 2 -8°C	Maximum payload temperature reached during tested duration (°C)
48	6.9°C @ 48 hours