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Design Qualification Report for the MaxPlus PharmaPack (3L, 36-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# 1RPPF36-3). 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 36 hours.

2. Shipper Specifications:

- Outer Shell Material: Corrugated Cardboard
- Outer Dimensions: 11.25in x 9.25in x 9.25in (LWH)
- Payload Dimensions: 8.5in x 6.5in x 2.5in (LWH)
- System Weight (excluding payload): 9.2 lbs.
- Phase Change Coolant:
 - NI-W8L9 (x2) (7.5" x 8.5" x 1")



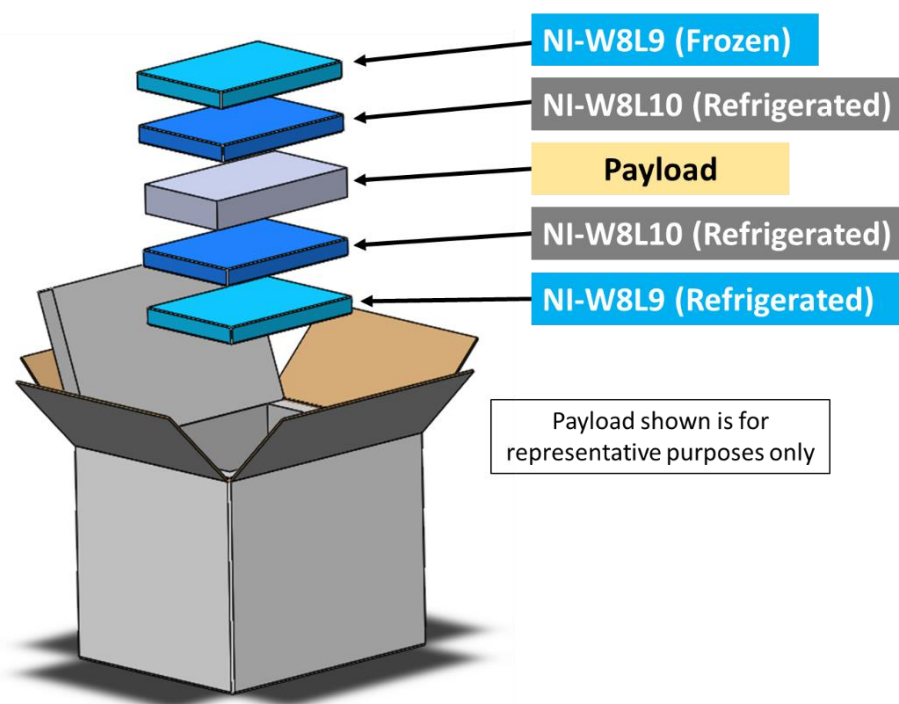
- NI-W8L10 (x2) (7.5" x 10.25" x 1.5")



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3. Packing Methods

3.1 Packout Schematic (Winter):



3.1.1 Winter Coolant Conditioning Procedure:

- 1 x Coolant NI-W8L9 (**White pouch with Blue marking – Nordic Ice**) stored in the freezer (below -10°C) for a minimum of 24 hours
- 1 x Coolant NI-W8L9 (**White pouch with Blue marking – Nordic Ice**) stored in the refrigerator (between 2°C to 8°C) for a minimum of 24 hours
- 2 x Coolant NI-W8L10 pouches (**White with Blue marking- Nordic Ice**) stored in the refrigerator (between from 2°C to 8°C) for a minimum of 24 hours

All frozen and refrigerated coolants should be used directly from the freezer or the refrigerator.

Note: *Make sure that the coolant NI-W8L9 pouch is frozen solid before removing it from the freezer.*

3.1.2 Packing Instructions (Winter):

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

Step 2: Insert one **refrigerated Coolant NI-W8L10** pouch (white/blue) on top of the refrigerated Coolant NI-W8L9 .

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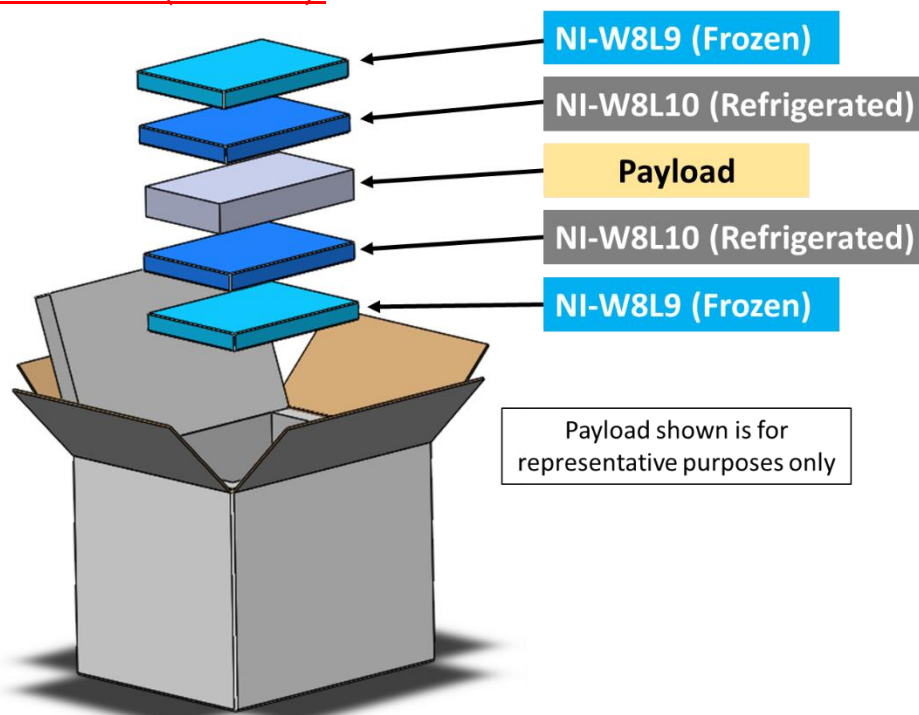
Step 3: Insert the **payload** on top of the refrigerated Coolant NI-W8L10 pouch.

Step 4: Insert the second **refrigerated Coolant NI-W8L10** on top of the payload.

Step 5: Place the last **frozen Coolant NI-W8L9** brick on top of the second Coolant NI-W8L10 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 pouch with Blue marking – Nordic Ice**) stored in the freezer (below -10°C) for a minimum of 24 hours
- 2 x Coolant NI-W8L10 pouches (**White with Blue marking- Nordic Ice**) stored in the refrigerator (between 2°C to 8°C) for a minimum of 24 hours

All frozen and refrigerated coolants should be used directly from the freezer or the refrigerator.

Note: Make sure that the coolant NI-W8L9 pouches are frozen solid before removing them from the freezer.

3.2.2 Packing Instructions (Summer):

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

Step 2: Insert one **refrigerated Coolant NI-W8L10** pouch (white/blue pouch) on top of the frozen coolant.

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Step 3: Insert the **payload** on top of the refrigerated Coolant NI-W8L10 pouch.

Step 4: Insert the second **refrigerated Coolant NI-W8L10** on top of the payload.

Step 5: Place the last **frozen Coolant NI-W8L9** brick on top of the second refrigerated coolant NI-W8L10.

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

4. Design Qualification Test Methods and Results:

4.1 Test Methods: The presented 1RPPF36-3 PharmaPack SP Shipper with PCM0 pouches is designed to maintain product between 2-8°C for a minimum of 36 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 36 hours. At the end of the test run, payload temperature data was downloaded and analyzed to assess the systems' performance.

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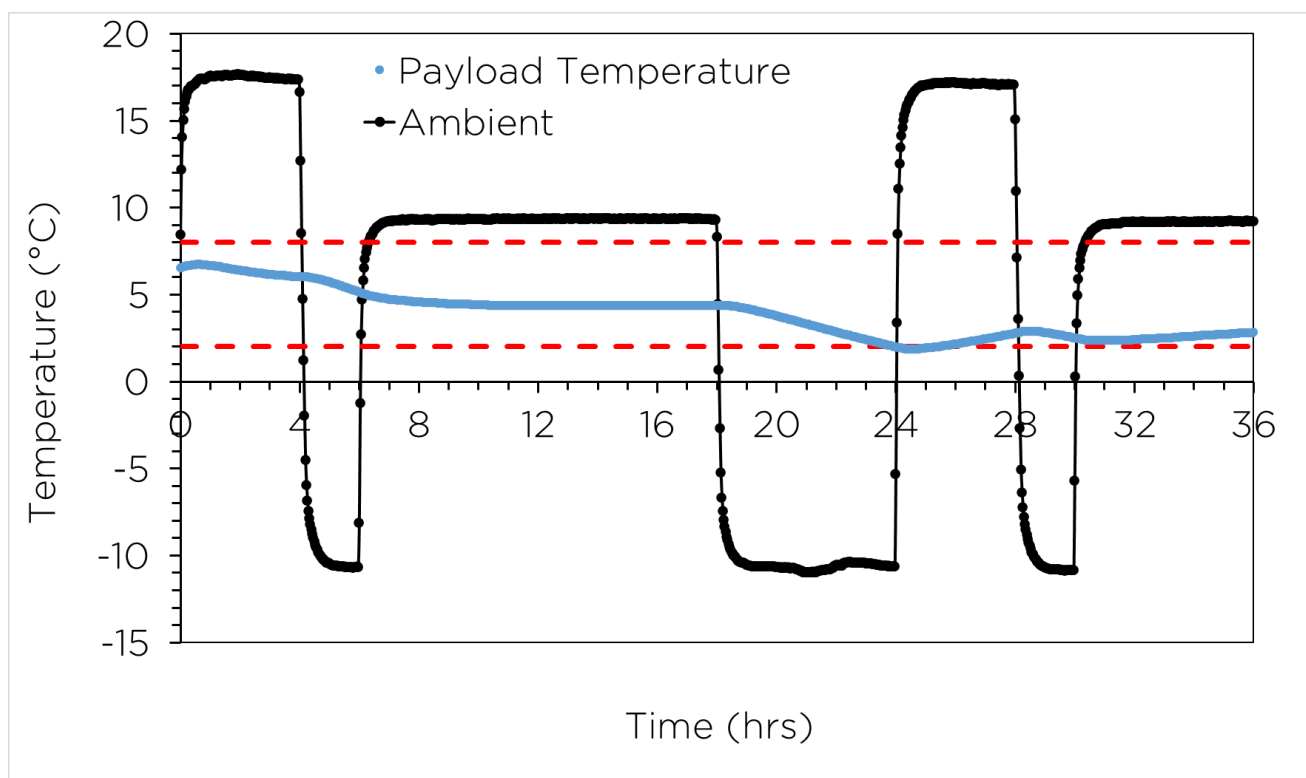
4.2 Test Results:

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 36 hours
Ambient temperature	Winter Ambient
Test duration	36 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
36	2°C @ 24.3 hours

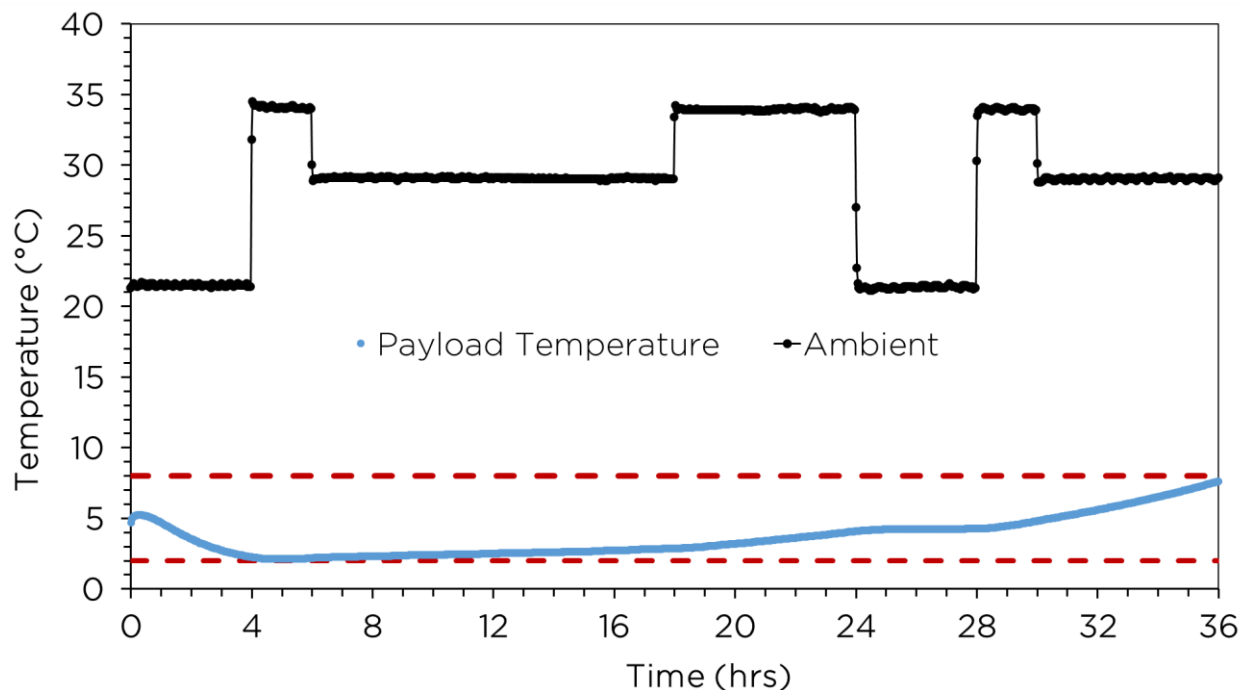
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4.2.2 Payload maintained at 2-8°C | **Summer Ambient**

Test setup:

Test payload	2 x 60mL water pouches kept at 2°C to 8°C for 36 hours
Ambient temperature	Summer Ambient
Test duration	36 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)
36	7.6°C @ 36 hours