Prepared by: Arif Rahman (Director of Technology),
Approved by: Saravan Kumar (CEO)

Design Qualification Report for the MaxPlus PharmaPack SP Shipper (SKU # 1RPPV36-2)

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

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1. Scope:

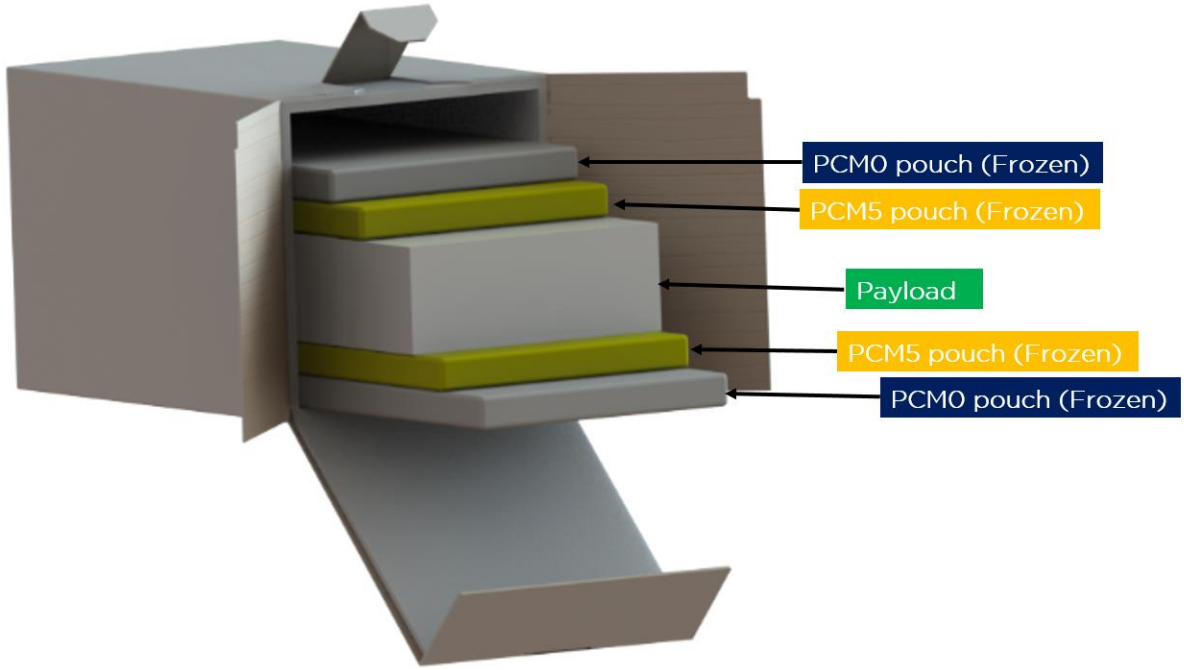
The scope of this Design Qualification (DQ) report is to summarize the components and thermal performance of the MaxPlus Small PharmaPack SP Shipper (SKU#1RPPV36-2) for refrigerated products. The report addresses shipper specifications, components breakdown, packing methods, and temperature compliance data for the 1RPPV36-2 to transport refrigerated specialty pharma products at 2-8◦C for a minimum of 24 hours.

2. Shipper Specifications:

- Outer Dimensions: 6in x 6in x 8.875in (LWH)
- Payload Dimensions: 8in x 5in x 2in (LWH)
- System Weight (excluding payload): 4.0 lbs.
- Phase Change Coolant: PCM0 (x2), PCM5 (x2)

3. Packing Methods

3.1 Summer Packout Schematic (1RPPV36-2):



Note: All coolant bricks are white in reality. The yellow pouches shown in the model are for visual representation only.

3.2 Summer Coolant Conditioning Procedure:

- 2 x PCM0 pouches stored in the freezer (-10°C to -30°C) for a minimum of 24 hours
- 2 x PCM5 pouches stored in the freezer (-10°C to -30°C) for a minimum of 24 hours
- After 24 hours, the PCMs are ready for use.
- To pack the shipper, take out **PCM0 pouch (x2)** and **PCM5 pouches (x2)** from the freezer and **condition them laying flat** on a benchtop for 30 minutes at room temperature.

  Note: *Make sure that the PCM0 and PCM5 pouches are frozen solid before removing them from the freezer. Don't stack the pouches on top of each other on the benchtop.*

3.3 Summer Packing Instructions:

Step 1: Insert one frozen PCM0 pouch (benchtop conditioned) into the PharmaPack.

Step 2: Insert one frozen PCM5 pouch (benchtop conditioned) on top of the frozen PCM0 pouch

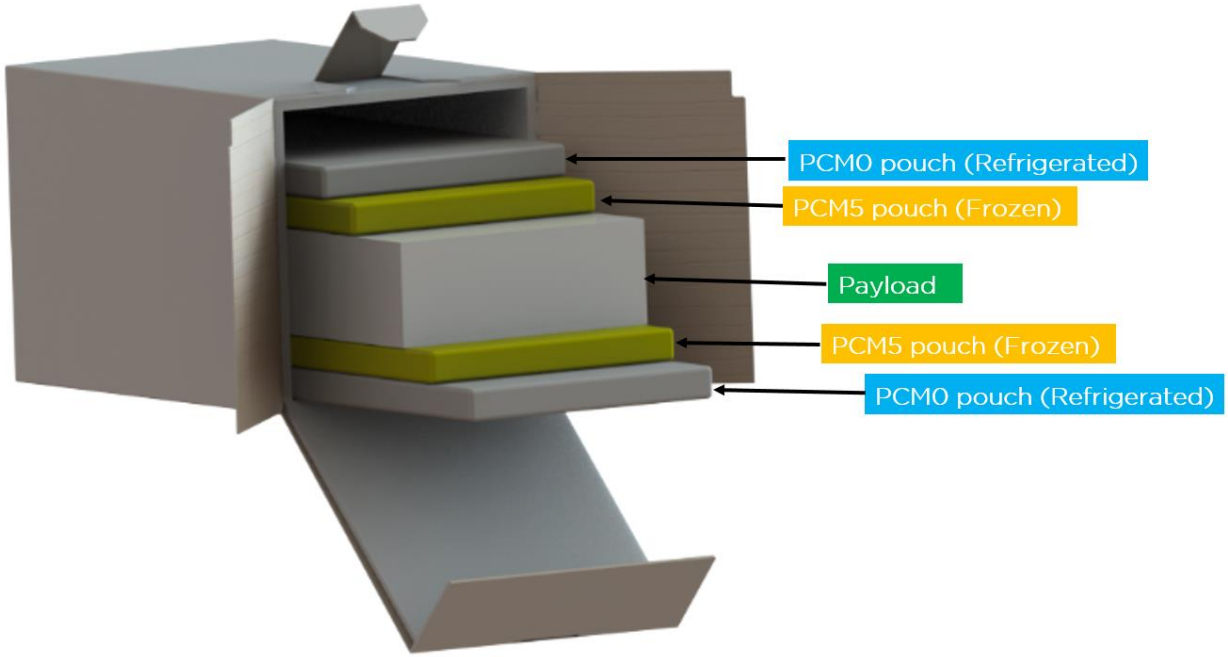
Step 3: Insert the payload on top of the frozen PCM5 pouch.

Step 4: Insert the second frozen PCM5 pouch (benchtop conditioned) on top of the payload.

Step 5: Place the last frozen PCM0 pouch (benchtop conditioned) on top of the PCM5 pouch.

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

3.4 Winter Packout Schematic (1RPPV36-2):



Note: All coolant bricks are white in reality. The yellow pouches shown in the model are for visual representation only.

3.5 Winter Coolant Conditioning Procedure:

- 2 x PCM0 pouches stored in the refrigerator (2°C to 8°C) for a minimum of 24 hours
- 2 x PCM5 pouches stored in the freezer (-10°C to -30°C) for a minimum of 24 hours
- After 24 hours, the PCMs are ready for use.
- To pack the shipper, take out **PCM5 pouches (x2)** from the freezer and **condition them laying flat** on a benchtop for 30 minutes at room temperature.

  Note: *Make sure that the PCM5 pouches are frozen solid before removing them from the freezer. Don't stack the pouches on top of each other on the benchtop.*

3.6 Winter Packing Instructions:

Step 1: Insert one refrigerated PCM0 pouch directly from the refrigerator into the PharmaPack.

Step 2: Insert one frozen PCM5 pouch (benchtop conditioned) on top of the PCM0 pouch

Step 3: Insert the payload on top of the frozen PCM5 pouch.

Step 4: Insert the second frozen PCM5 pouch (benchtop conditioned) on top of the payload.

Step 5: Place the last refrigerated PCM0 pouch from the refirgerator on top of the PCM5 pouch.

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

4. Design Qualification Test Methods and Results:

4.1 Test Methods: The presented 1RPPV36-2 PharmaPack SP Shipper with PCM0 (x2) and PCM5 (x2) pouches is designed to maintain product between 2-8°C for a minimum of 24 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.

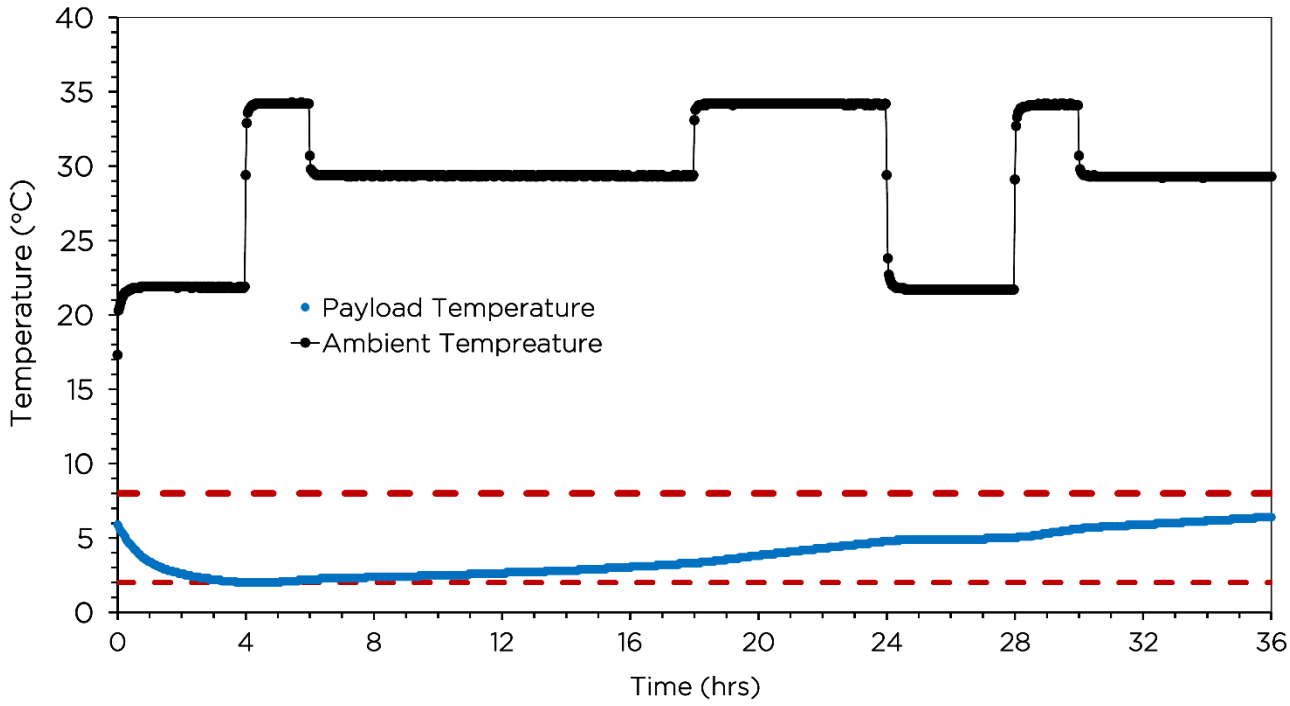
4.2 Test Results:

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

Test setup:

Test payload	2 x 30mL water pouches kept at 2°C to 8°C for 12 hours
Ambient temperature	Summer Ambient
Test duration	36 hours

Thermal performance plot:



Observations: The following table summarizes payload temperature data.

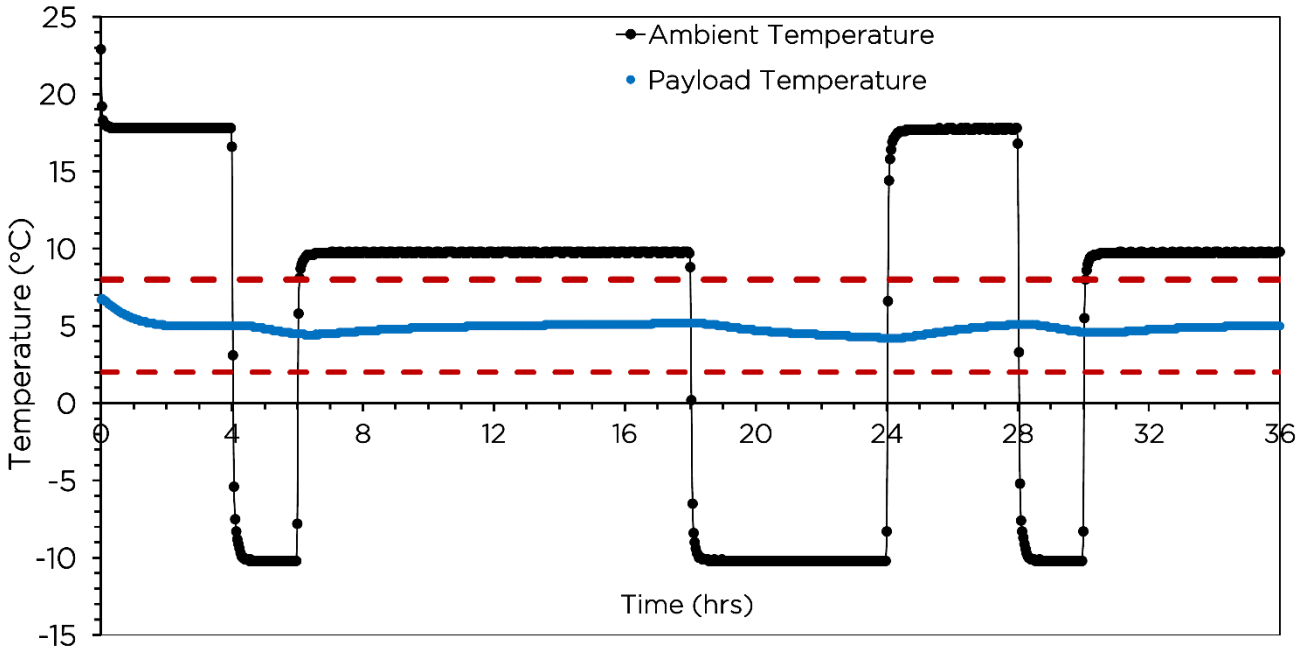
Total time (hours) payload-maintained 2 - 8°C	**Maximum payload temperature reached during tested duration**
36 hours	6.4°C @ 36 hours

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

Test setup:

Test payload	2 x 30mL water pouches kept at 2°C to 8°C for 12 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 (°C)**
36 hours	4.2°C @ 23.8 hours

Revision History: