



The Crucial Role of Ambient Profiles In Ensuring Reliable Cold Chain Packaging for Specialty Pharmacy Medication

AUTHORS: Dr. Saravan Kumar, Dr. Arif Rahman, Dr. Quyen Dinh, Mr. George Jett. *Thermal Engineering Team, MaxQ.*

Abstract

In the rapidly evolving landscape of specialty pharmacy, where the timely and safe delivery of temperature-sensitive medications is paramount, selecting the right cold chain packaging becomes a critical concern. Many pharmacies, however, inadvertently overlook a crucial factor that underpins the effectiveness of such packaging—ambient profiles. This white paper delves into the significance of ambient profiles in the selection of risk mitigating cold chain packaging for specialty pharmacy medication. It highlights the common misperception surrounding packaging qualification claims and advocates for a more informed approach to packaging selection based on rigorous testing against realistic ambient conditions. By comprehending the interplay between packaging specifications, ambient profiles, and real-world shipping challenges, specialty pharmacies can better safeguard their shipments of sensitive medications while ensuring optimal cost-efficiency.



CONTACT



packmaxq.com



(405) 466-5629



sales@packmaxq.com



Table of contents

01 Introduction



02 The Deceptive World of Packaging Qualification Claims



03 Understanding Industry Standard Ambient Profiles



04 Leveraging Ambient Profiles: Beyond Industry Norms



05 The Imperative of Informed Selection



06 Experimental Insights: Unmasking Performance Discrepancies



07 Conclusion: The Path Forward

THE CRUCIAL ROLE OF AMBIENT PROFILES IN ENSURING RELIABLE COLD
CHAIN PACKAGING FOR SPECIALTY PHARMACY MEDICATION

1


Introduction: **The Unseen Vulnerability in Cold Chain Shipping**




Ensuring the **integrity** of temperature-sensitive medications during shipping is **paramount**

*In the complex ecosystem of specialty pharmacy, ensuring the integrity of temperature-sensitive medications during shipping is **paramount**.* However, amidst the sea of packaging options and qualification claims, a critical yet often overlooked factor emerges. The ambient profile under which these packaging solutions are tested. As pharmacies grapple with the balance between cost and risk mitigation, the role of ambient profiles in driving effective packaging solutions warrants careful consideration.

THE CRUCIAL ROLE OF AMBIENT PROFILES IN ENSURING RELIABLE COLD
CHAIN PACKAGING FOR SPECIALTY PHARMACY MEDICATION



The Deceptive World of Packaging Qualification Claims



The **Deceptive** World of Packaging Qualification Claims

Packaging solutions often boast impressive qualification claims, citing durations of 36/48/72 hours. Unfortunately, these claims can be misleading, as they typically stem from testing against the mildest of ambient conditions. The real-world shipping scenarios are far more severe, with extreme high and low temperatures based on geography and seasonal weather conditions, when compared to some of the ambient conditions used in design and testing. The consequence? Higher risk of temperature excursions that jeopardize the efficacy of expensive medications and patient safety.

THE CRUCIAL ROLE OF AMBIENT PROFILES IN ENSURING RELIABLE COLD
CHAIN PACKAGING FOR SPECIALTY PHARMACY MEDICATION

Understanding Industry Standard Ambient Profiles



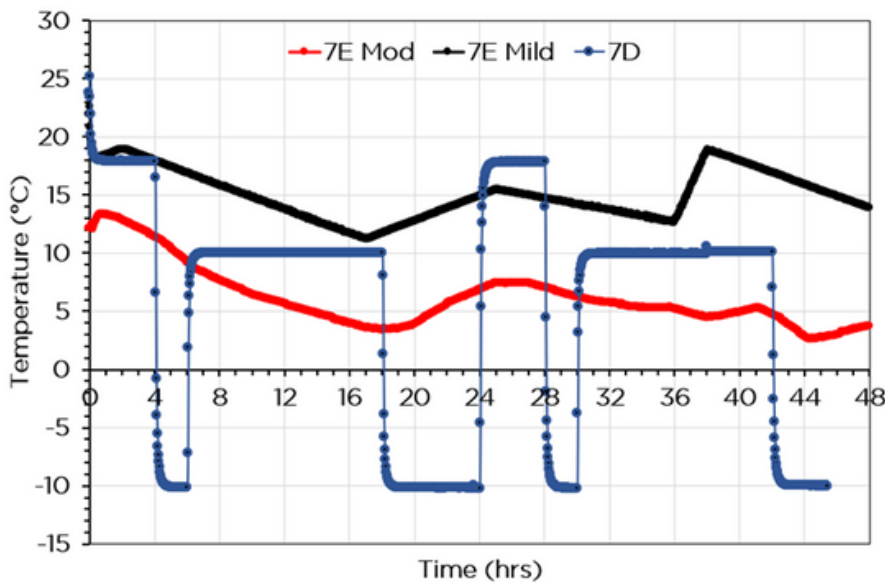
Understanding **Industry Standard** Ambient Profiles

The International Safe Transit Association (ISTA) has formulated four standard ambient profiles—ISTA 7D, ISTA 7E mild, ISTA 7E medium, and ISTA 7E severe. The table and graph below detail the different temperature profiles. These profiles, meticulously developed using real-world shipping lane data, stand as the gold standard for packaging specification in the biopharma industry. Drug manufacturers align their packaging testing to these profiles to assess their cold chain packaging designs' resilience against the challenges of varied shipping environments. MaxQ tests our packaging against ISTA 7D standards, whereas other packaging providers test against ISTA 7E mild standards. In doing so, we are confident that our packaging solutions are capable of handling extreme weather conditions.

Figure 1. Industry standard ambient temperature profiles commonly used to design cold chain shipping containers. A) Summer, B) Winter season ambient profiles for 48 hours. Both the graphs are showing three different standards – ISTA 7E mild, 7E moderate and 7D.

A) Winter Profiles

ISTA Profiles used in this study - Winter

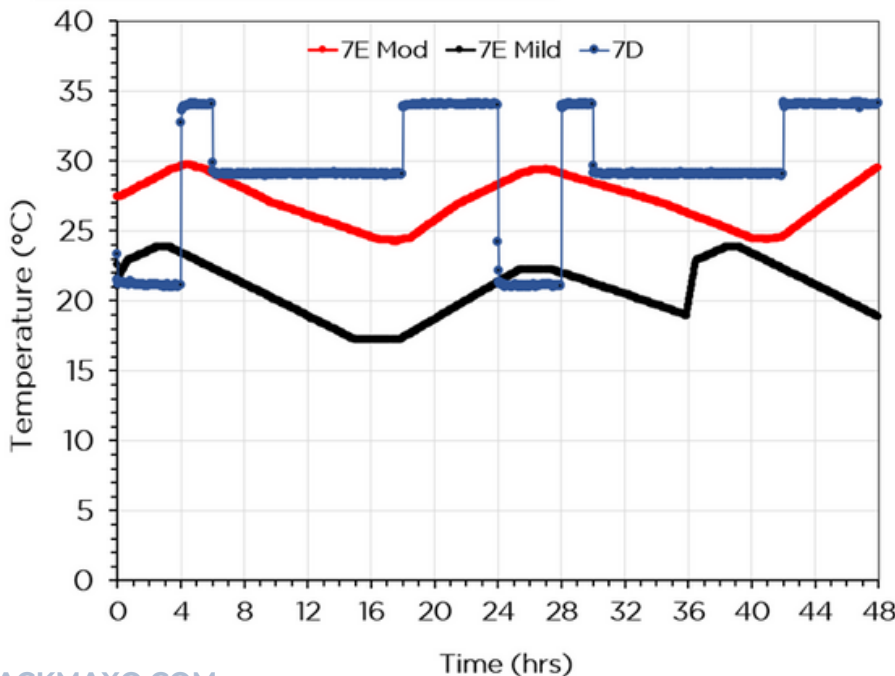


Profile Summary

ISTA Profile	Max	Min	Average
7E Mild	23°C	11°C	15°C
7E Moderate	20°C	3°C	9°C
7D	18°C	-10°C	10°C

B) Summer Profiles

ISTA Profiles used in this study - Summer



Profile Summary

ISTA Profile	Max	Min	Average
7E Mild	24°C	17°C	20°C
7E Moderate	30°C	24°C	27°C
7D	35°C	22°C	30°C

THE CRUCIAL ROLE OF AMBIENT PROFILES IN ENSURING RELIABLE COLD
CHAIN PACKAGING FOR SPECIALTY PHARMACY MEDICATION



Leveraging Ambient Profiles: Beyond Industry Norms



Leveraging Ambient Profiles: **Beyond Industry Norms**

Some drug manufacturers transcend the industry standard by devising custom, lane-specific ambient profiles. In other words, a lot of work is put into developing “Distribution Relevant Ambient” profiles which are then used to design, select, and qualify packaging designs. These profiles mirror the intricacies of their unique shipping routes, offering a more precise simulation of the conditions encountered during transit. The benefits of this approach extend beyond regulatory compliance; they encompass operational efficiency and enhanced performance, elevating the standard of protection and minimizing risk. Given the complexity of Specialty Pharmacy operations and the unique challenges of direct-to-patient last mile shipments, this approach provides essential data and insight to help achieve these goals.



Leveraging Ambient Profiles: **Beyond Industry Norms**

Navigating the intricate world of specialty pharmacy distribution, one quickly realizes the challenge: the vast expanse of geography and the intricate web of shipping routes. Couple this with the unpredictability of weather, with temperatures swinging from sweltering highs to freezing lows, and it becomes evident that crafting a universal ambient profile for packaging qualification is akin to chasing a mirage.

Even a pharmacy that operates on a local or regional scale can find benefits from this level of sophistication and data analysis. To develop a clear picture, our team at MaxQ embarked on a meticulous analysis of historical weather data across the entirety of mainland United States for the last 5-years (3 of which are the hottest recorded years). Our aim was to identify the extremes, to see how weather patterns compared to the industry-standard ISTA ambient profiles.



Leveraging Ambient Profiles: **Beyond Industry Norms**

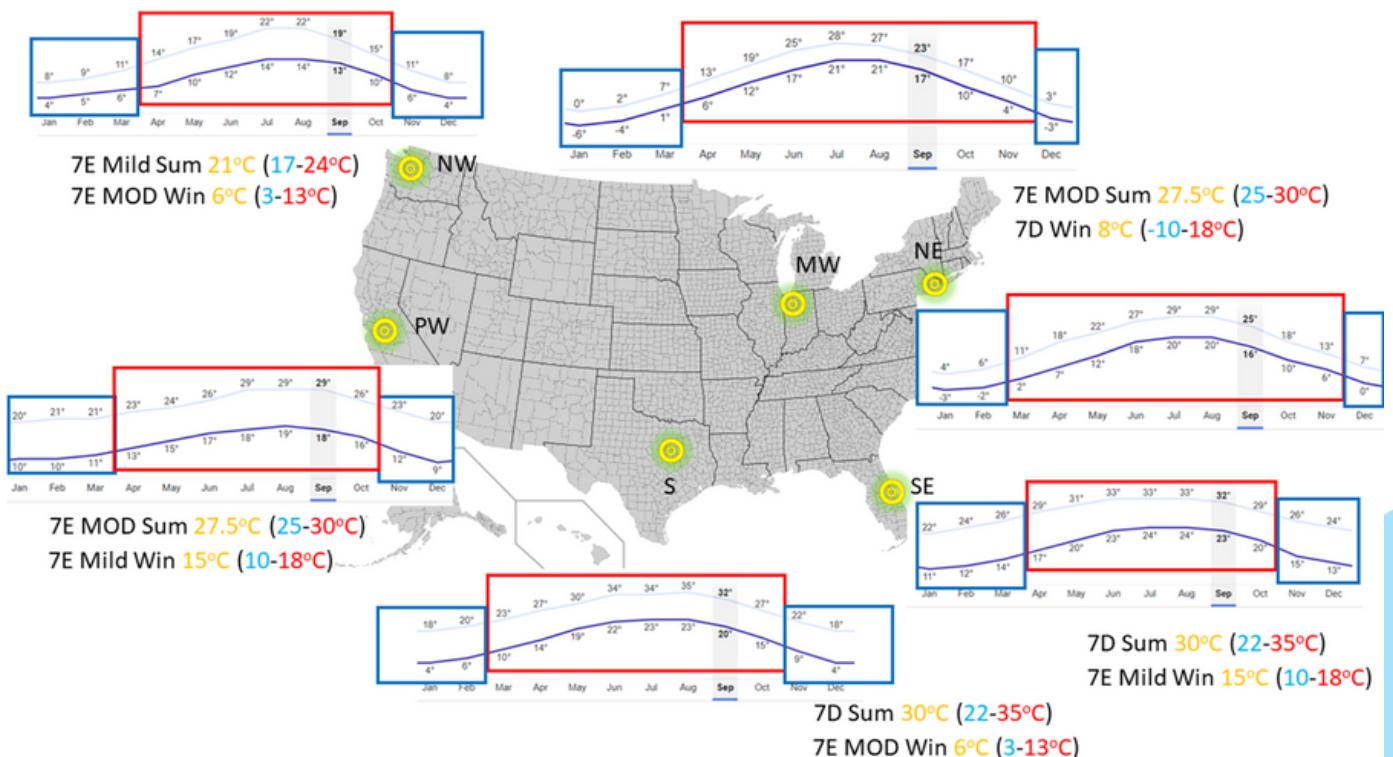
Though the ambient temperatures that a packaging sees is not exactly same as the weather, this was just an attempt to gain a global picture. What emerged was a vivid tapestry of regional nuances, each area exhibiting its unique ambient temperature characteristics (Figure 2).

This data underscores a critical truth: for specialty pharmacies, there's no one-size-fits-all solution. Instead, they must invest time and effort to develop their own "distribution-relevant ambient" to guide their packaging choices. This scientific approach not only enhances product safety but also elevates the overall patient experience, reinforcing trust in the specialty pharmacy's vital services.

Leveraging Ambient Profiles: **Beyond Industry Norms**



Figure 2. Regional high and low temperatures and corresponding industry standard ISTA 7D/7E profile that closely matches the average temperature in each region. For instance, the regional weather in North West region (NW) matches ISTA 7E mild summer profile and 7E moderate winter profile.



THE CRUCIAL ROLE OF AMBIENT PROFILES IN ENSURING RELIABLE COLD
CHAIN PACKAGING FOR SPECIALTY PHARMACY MEDICATION

5

The Imperative of Informed Selection

The Imperative of Informed Selection



For specialty pharmacies, the selection of cold chain packaging must extend beyond cost-consciousness. A thorough understanding of ambient profiles equips pharmacies with the knowledge needed to make strategic decisions that balance risk and expenditure. By aligning packaging specifications with the most relevant and rigorous ambient profile, pharmacies can elevate the reliability of their shipments and uphold the integrity of the medications they deliver. This can have a profound and positive impact on patient safety and customer satisfaction.

THE CRUCIAL ROLE OF AMBIENT PROFILES IN ENSURING RELIABLE COLD
CHAIN PACKAGING FOR SPECIALTY PHARMACY MEDICATION



Experimental Insights: Unmasking Performance Discrepancies



Experimental Insights: Unmasking **Performance Discrepancies**

In the pursuit of quantifying the effect of ambient profiles in designing and selecting cold chain shipping boxes, we undertook a comprehensive experimental study. The intention of this study was not to study every single packaging design or materials or pack-out procedures. The primary goal was to highlight the risk of choosing packaging solutions that are not built to withstand more rigorous ambient test standards.

The two most commonly used cold chain packaging designs by specialty pharmacies are expanded polystyrene (EPS) insulation molded shippers and curbside recyclable (starch, paper or fiber based) insulation 2-piece flexible liners. Most solutions are built to withstand the low thermal stress profiles – 7E mild or moderate. In this comparative study, we chose five different packaging solutions that cover the spectrum of different materials, pack-outs and built against different ambient standards. Coolant conditioning and pack-out procedures (for both summer and winter) were obtained from public reports and from pharmacies that are currently using these packages.

Experimental Insights: Unmasking **Performance Discrepancies**



The packaging solutions were subjected to a battery of tests, exposing them to three distinct ambient profiles—ISTA 7E mild, ISTA 7E medium, and ISTA 7D summer and winter profiles for a maximum duration of 48 hours. This meticulous investigation was conducted within a precisely calibrated environmental chamber, designed to replicate the diverse challenges encountered during real-world shipping scenarios. The details of the shippers chosen for this study are listed below:

Table 1. Details of boxes chosen for this study. The four boxes represent the most common materials and designs used widely in the industry.

Box	Description	Dimensions	Coolants and conditioning	Design claim
1	Molded Styrofoam container (Size 1)	Outer dims: 11.75" x 11.75" x 11.75" (LWH) Payload capacity: 5.2 L	3 x 36 Oz gel packs frozen below 0C for 24 hours	36 hours, ISTA 7E mild
2	Molded Styrofoam container (Size 2)	Outer dims: 11.25" x 9.25" x 12.5" (LWH) Payload capacity: 4.3 L	3 x 36 Oz gel packs frozen below 0C for 24 hours	36 hours, ISTA 7E mild
3	Curbside recyclable 2-piece liner solution	Outer dims: 12.25" x 12.25" x 12.25" (LWH) Payload capacity: 10.3 L	3 x 36 Oz gel packs frozen below 0C for 24 hours	36 hours, ISTA 7E mild
4	Reflective foam 2-piece liner	Outer dims: 11.25" x 9.25" x 9.25" (LWH) Payload capacity: 3 L	2 x 36 Oz gel packs frozen below 0C for 24 hours. 30-minute bench time conditioning before packing.	36 hours, ISTA 7D
5	Vacuum insulated packaging design	Outer dims: 11.25" x 9.25" x 9.25" (LWH) Payload capacity: 4 L	4 x 16 Oz gel packs frozen below 0C for 4 hours. 30-minute bench time conditioning before packing.	48 hours, ISTA 7D



Methodology: A Rigorous Examination

The packaging solutions, each with its own set of manufacturer claims, were exposed to the predefined ambient profiles in a controlled environment. The ambient profiles, established by the International Safe Transit Association (ISTA), represent a spectrum of shipping conditions—ranging from mild to severe (7E)—and ISTA 7D, representing a stable distribution environment (Figure 1). The temperature of simulated product was monitored continuously using a NIST calibrated digital temperature data logger to record any deviations from the prescribed thresholds and assess the point of failure (Pre-qualified shipping duration).



Results: **Unveiling Discrepancies**

The outcomes of the experiment painted a clear picture of the packaging solutions' performance against varying ambient profiles. Tables 2 and 3 below summarize the thermal performance for all 5 boxes against the 3 different summer and winter ambient profiles. As the severity of the ambient conditions increased—from mild to medium to severe—the packaging solutions demonstrated a strikingly varied ability to uphold the prescribed internal temperature thresholds. This is consistent with feedback that we have received from numerous specialty pharmacies who have encountered inconsistent, undesirable performance from their packaging solutions. On the other hand, the two packaging solutions that were designed from the get go against the more severe ambient profile demonstrated a robust performance against all tested ambient profiles.



Results: **Unveiling Discrepancies**

The outcomes of the experiment painted a clear picture of the packaging solutions' performance against varying ambient profiles. Tables 2 and 3 below summarize the thermal performance for all 5 boxes against the 3 different summer and winter ambient profiles. As the severity of the ambient conditions increased—from mild to medium to severe—the packaging solutions demonstrated a strikingly varied ability to uphold the prescribed internal temperature thresholds. This is consistent with feedback that we have received from numerous specialty pharmacies who have encountered inconsistent, undesirable performance from their packaging solutions. On the other hand, the two packaging solutions that were designed from the get go against the more severe ambient profile demonstrated a robust performance against all tested ambient profiles.

Results: Unveiling Discrepancies



Table 2. Thermal performance results for all 5 tested boxes against the 4 different ambient conditions – summer hot cycle, 48 hours.

Box	Description	7E mild	7E moderate	7D
1	Molded Styrofoam container (Size 1) - <u>Claim</u> : 48 hours	Payload went below 2°C at 1.6 hours	Payload went below 2°C at 1.8 hours	Payload went below 2°C at 2 hours
2	Molded Styrofoam container (Size 2) - <u>Claim</u> : 36 hours	48 hours	45.2 hours	39.6 hours
3	Curbside recyclable 2-piece liner solution - <u>Claim</u> : 36 hours	Payload went below 2°C at 1.2 hours	Payload went below 2°C at 1.94 hours	Payload went below 2°C at 1.7 hours
4	Reflective foam 2-piece liner <u>Claim</u> : 36 hours	48 hours	41.6 hours	38 hours
5	Vacuum insulated packaging design - <u>Claim</u> : 48 hours	48 hours	48 hours	48 hours

Table 3. Thermal performance results for all 5 tested boxes against the 4 different ambient conditions – winter cold cycle, 48 hours.

Box	Description	7E mild	7E moderate	7D
1	Molded Styrofoam container (Size 1) - <u>Claim</u> : 36 hours	48 hours	19.4 hours	19.6 hours
2	Molded Styrofoam container (Size 2) - <u>Claim</u> : 36 hours	48 hours	45.2 hours	39.6 hours
3	Curbside recyclable 2-piece liner solution - <u>Claim</u> : 36 hours	43 hours	48 hours	Payload went above 8C at 0.1 hour
4	Reflective foam 2-piece liner <u>Claim</u> : 36 hours	43.4 hours	48 hours	38.5 hours
5	Vacuum insulated packaging design - <u>Claim</u> : 48 hours	48 hours	48 hours	48 hours



Interpretation: **Navigating the Disparity**

The observed disparity between packaging claims and actual performance underlines the necessity for a shift in the approach to packaging selection. When choosing cold chain packaging, relying solely on manufacturer claims without paying attention to the tested ambient profiles can result in an underestimation of the risks posed by demanding ambient conditions. While the allure of cost savings may be enticing, the consequences of compromised medication integrity due to inadequate packaging far outweigh the initial savings. The experimental insights from this study underscore the importance of ambient profiles used while designing, testing and selecting suitable cold chain packaging solutions. The 3 ambient profiles used in this study is not meant to cover all extremes that a packaging could face during last mile shipping. Instead, these standards serve as a starting point to develop a robust design. Properly selected packaging should still undergo performance qualification (PQ) testing to ensure that there are no unnoticed extreme temperature risks in real-world conditions.



Interpretation: **Navigating the Disparity**

As specialty pharmacies tread the delicate balance between cost efficiency and risk mitigation, understanding the stark divergence between packaging claims and performance is paramount. By aligning packaging choices with the most demanding of ambient profiles, pharmacies can insulate themselves against unforeseen challenges, reduce product loss risk, and ensure the reliable delivery of medications to patients.

THE CRUCIAL ROLE OF AMBIENT PROFILES IN ENSURING RELIABLE COLD
CHAIN PACKAGING FOR SPECIALTY PHARMACY MEDICATION

7

Conclusion: The Path Forward

Conclusion: **The Path Forward**

In the relentless pursuit of excellence within specialty pharmacy, the role of ambient profiles in cold chain packaging emerges as a defining factor. As pharmacies face the dual challenge of cost management and risk mitigation, the judicious selection of packaging solutions—tested against the most realistic ambient conditions—offers a tangible solution. By understanding the nuances of ambient profiles and aligning their packaging choices accordingly, pharmacies can confidently navigate the intricate cold chain landscape and safeguard the health and well-being of their patients.

SCHEDULE YOUR FREE RISK ASSESSMENT

Start your cold chain packaging journey with a knowledge check. Assess your current packaging against real-world shipping challenges. Schedule a free risk assessment meeting today for your specialty pharmacy's unique needs. Improve medication shipment reliability and minimize temperature risks. Your patients' well-being and trust are our top priorities.

CONTACT US



packmaxq.com



(405) 466-5629



sales@packmaxq.com