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From the Blog

Environmental Conditioning

October 13th 2026

Medical devices and pharmaceutical products may encounter varying temperature and humidity conditions throughout storage, handling, and distribution. These environmental factors can influence the physical and mechanical properties of packaging materials, potentially affecting their ability to protect products during transportation.

Environmental Conditioning provides a controlled method for exposing packaging systems to specified climatic conditions before subsequent testing. Performed according to ASTM D4332, this process helps manufacturers evaluate packaging behavior under defined environmental exposures and supports the development of reliable packaging validation strategies.

Understanding Environmental Conditioning and ASTM D4332

ASTM D4332, Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing, establishes procedures for conditioning packaging specimens under specified temperature and relative humidity conditions.

Packaging materials, particularly paperboard, corrugated cardboard, and certain polymers, may respond differently to climatic variations. Changes in temperature and humidity can influence mechanical strength, stiffness, dimensional stability, and other material properties.

Under ASTM D4332, packaging specimens are exposed to selected environmental conditions for an appropriate duration, allowing them to approach or reach equilibrium with the specified atmosphere. This establishes a reproducible basis for subsequent testing and helps manufacturers assess packaging performance under controlled conditions.

Environmental Conditioning is frequently incorporated into distribution simulation programs, where climatic exposure may influence packaging behavior during subsequent mechanical testing.

Environmental Conditioning in Packaging Validation

Environmental Conditioning can be integrated into broader packaging validation and distribution simulation programs. ASTM D4169, Standard Practice for Performance Testing of Shipping Containers and Systems, establishes procedures for evaluating packaging performance under distribution hazards, including vibration, compression, and shock.

When combined with ASTM D4169, Environmental Conditioning allows packaging specimens to undergo defined climatic exposure before selected mechanical tests. This helps manufacturers identify potential weaknesses in packaging materials or configurations that could affect performance during transportation.

For terminally sterilized medical devices, Environmental Conditioning may also support packaging validation activities aligned with ISO 11607-1:2019, including Amendment 1:2023 concerning the application of risk management.

While conditioning alone does not demonstrate packaging integrity or regulatory compliance, it provides supporting evidence within a broader testing strategy that may include distribution simulation, seal strength, and package integrity testing.



Environmental Conditions and Testing Profiles

ASTM D4332 defines standard and special conditioning atmospheres that can be selected according to the packaging materials, anticipated distribution environment, and testing objectives. The following table presents examples of environmental conditions used in conditioning protocols:

Environmental Condition	Temperature (°C, °F)	Relative Humidity (%RH)
Extreme cold	-30 ± 2 (-22 ± 4)	Uncontrolled
Frozen	-18 ± 2 (0 ± 4)	Uncontrolled
Refrigerated	5 ± 2 (41 ± 4)	85 ± 5
Temperate, high humidity	20 ± 2 (68 ± 4)	90 ± 5
Tropical	40 ± 2 (104 ± 4)	90 ± 5
Desert	60 ± 2 (140 ± 4)	15 ± 5

These controlled exposures allow manufacturers to investigate how packaging materials respond to different climatic stresses. For example, high humidity may reduce the compression resistance of corrugated packaging, while temperature variations can influence the flexibility or stiffness of certain polymer-based components. The selection of conditioning parameters and exposure duration should be justified according to the intended testing protocol.



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Supporting Packaging Performance Throughout Distribution

Environmental Conditioning helps manufacturers understand how temperature and humidity can influence packaging behavior under controlled testing conditions.

By integrating climatic exposure into packaging testing programs, manufacturers can assess material performance, identify potential vulnerabilities, and support packaging design and validation decisions.

At Medistri, Environmental Conditioning forms part of our packaging testing capabilities, supporting healthcare manufacturers in evaluating packaging performance under specified environmental conditions.

To learn more about Medistri's Environmental Conditioning, visit our website [here](#) or contact us at contact@medistri.com.

— The Medistri Team

