

COLD CHAIN QUALIFICATION LABORATORY SERVICES

Micom Laboratories Inc. offers cold chain qualification services to insure you meet FDA, Health Canada, WHO and any other regulatory requirements in maintaining your product's label temperature throughout the complete shipping process. Our customer base for cold chain qualification services consists of major pharmaceutical companies throughout North America. Our complementary packaging tests services allow us to not only make sure your isothermal packaging will maintain the product's label temperature but will also properly survive the shipping hazards. Our 11000 square feet laboratory is staffed with highly experienced professionals, lab technicians and state-of-the-art equipment.

TEMPERATURE CHAIN QUALIFICATION TEST SERVICES:

Our ISTA certified laboratory is one of the very few truly independent third party laboratories in North America that does cold chain qualification as well as other test services without selling any packaging products. We can execute test protocols for your temperature chain qualification needs with our fully programmable walk-in chambers that can hold anything from small parcels up to multiple LD-3 aircraft containers. For smaller pack-outs and long term stability studies we can also use one of our many reach-in units. Using our Agilent VEE-Pro[®] powered proprietary computer interface we will accurately monitor your payload's temperature at strategically located positions while it is being cycled through the temperature profiles that simulate foreseeable temperature extremes your product might be exposed to during shipping.

We can measure up to 256 temperature points simultaneously on a continuous basis with accuracy traceable to national Standards (NIST). For calibration purposes we use a GE-Kaye IRTD (NIST traceable) with an accuracy of $\pm 0.005^{\circ}\text{C}$. All our thermocouples are high accuracy type T Kaye thermocouples.



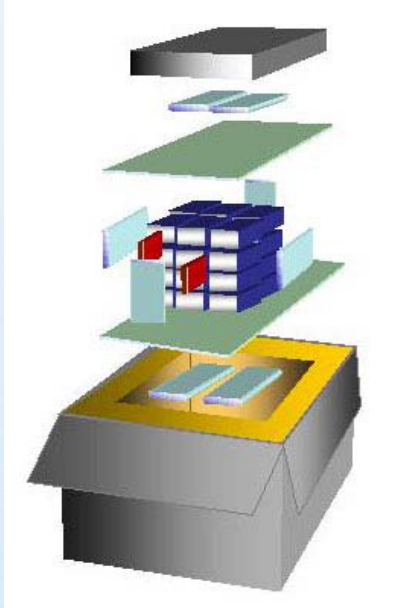
COLD CHAIN QUALIFICATION DRIVING FORCES:

What drives the market? Is cold chain qualification a buzz word? The answer is no. Drugs and medications need to be thermally protected in relation to their stability data for the very same reasons that you have to do stability data. Although this evidence is self supporting, it has been formally recognized by many Trade and Governmental agencies namely:

- Health Canada (guide 0069)
- FDA
- PDA (Technical bulletin 39)
- World Health Organization
- ISTA 7D (International Safe Transit Association)

START UP KIT:

Below is a list of key issues to which you need answers when you want to initiate a cold chain project:



- Temperature profile
- Test duration
- Number of different pack-outs to be tested
- Number of replicates (usually 3)
- Counts and dimensions
- Number of thermocouples
- Gel conditioning temperature

COLD CHAIN QUALIFICATION PROCESS:

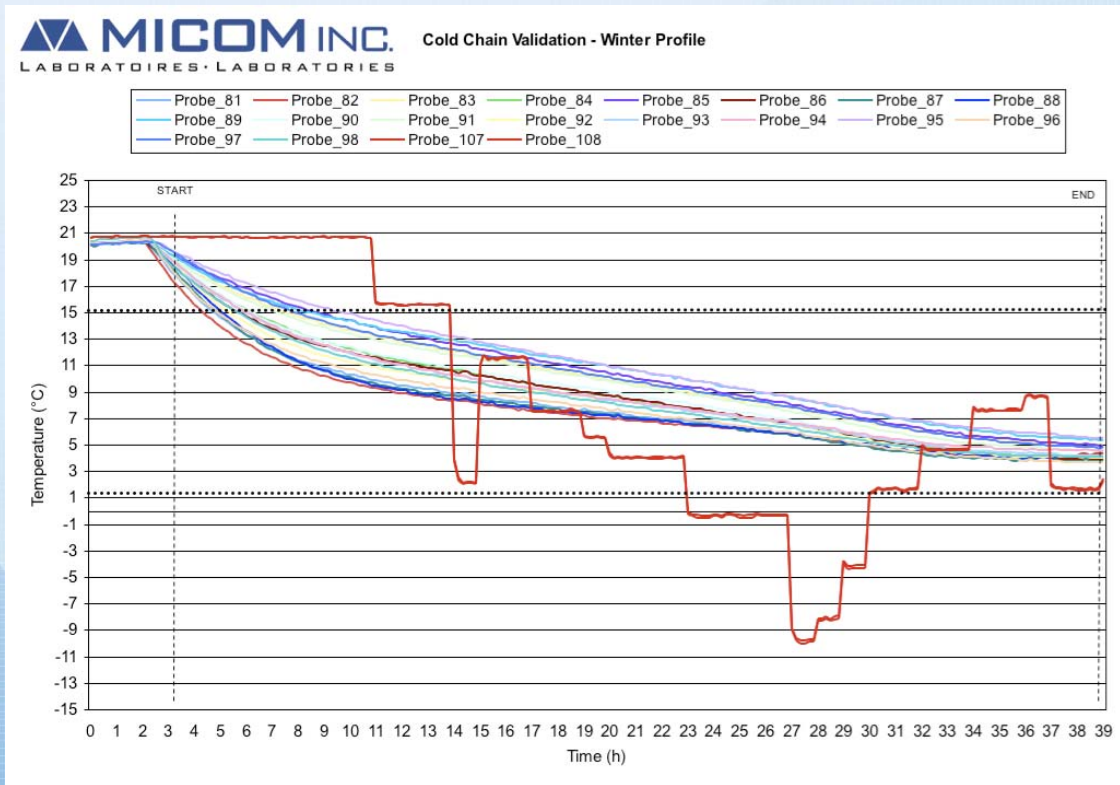
Your cold chain qualification process starts with your product's label temperature and its stability data. You then need to establish what the temperature profiles are that you want your pack-out to be challenged with. These temperature profiles should be typical of the most reasonable worst case conditions your product will encounter during normal distribution. Usually people need to run a winter and a summer temperature profile on their pack-outs. Most of the time the winter and summer pack outs are different. Few customers also have a spring/fall pack-out. You also need to bracket the number of doses you want to ship at once; the smallest and the largest number of doses each pack-out design may contain.

Once this is established, you can either try to design your own pack-out if you feel you have the proper expertise, or you can save yourself lots of headaches and lab costs and hire a consultant who will design your pack-out and help you with your temperature profiles.

Once you have established your product sensitivity, what your minimum and maximum payloads for each pack-out are and your temperature profiles, you can have your pack-out designed and then tested.

COLD CHAIN QUALIFICATION DELIVERABLES:

Through our testing we will demonstrate that your product can stay within its label temperature range using the proposed package when exposed to foreseeable temperature extremes. Our exhaustive test reports contain all the relevant information and technical data necessary to be able to accurately repeat any part of the testing performed to establish your pack-out cold chain qualification. Our reports will also have all of the relevant information for packing the product according to the successful pack-out schemes (packaging, icing, dunnage) including color photographs for each step of the pack-out operation. Our reports will also have all calibration and raw data as well as temperature curves graphically demonstrating your product's cold chain qualification compliance with its products temperature label under the temperature profile specified.



- Typical temperature profile -

Beyond the COLD CHAIN

MATERIAL TESTING SERVICES:

Micom Laboratories Inc. offers routine and non-routine material testing for a wide range of materials and products. Whether it is for temperature and humidity cycling, ultraviolet exposure, surface finishes, packaging testing or mechanical properties, our material testing experts will be happy to help you put together a meaningful test plan that will address your needs and give you real answers. With years of specialized technology testing expertise, in-depth experience and absolute commitment to customer care, our team of experts does more than simply test your products. Micom Laboratories Inc. strives to deliver material testing services of outstanding value to our diverse customer base.

SPECIFIC MATERIAL TESTING SERVICES:

Micom offers a wide variety of mechanical and physico-chemical material testing according to various standards (ASTM, CGSB, ISTA, ANSI, CSA, Bombardier & others). Our specialists can also provide you with custom material testing services focused on your specific needs.

Our facilities allow us to test a wide range of raw materials and finished products. Whether you need temperature chain testing, consumer products, composite materials, or accelerated ageing Micom's staff is always available to support your technical needs.

Our facilities are also equipped to test prototypes, simulate intensive use of products and materials either to validate your design or investigate a field failure. Our quality control system complies with ISO 17025.

THE TEST METHODS AND SERVICES OFFERED INCLUDE:

SURFACE FINISHES:

- Weatherometry, U.V. exposure (ASTM G-155)
- Environmental testing (Humidity, temperature cycling)
- Taber Abrasion (ASTM D-4060)
- Gloss (ASTM D-523)
- Salt spray (ASTM B-117)
- Scratch resistance (ASTM D-3363)
- Adhesives (ASTM C-297)

MATERIAL PROPERTIES:

- Tensile Strength (ASTM D-638, D-1623, D-2990, D-5574)
- Compressive Strength (ASTM D-695, D-2990, D-4762)
- Flexural Strength (ASTM D-790, D3043, D-5616)
- Foam (ASTM D-3574)
- Latex gloves (ISO-10282 & 11193)
- Moisture Absorption ASTM D-570
- Particle Board Testing ASTM D-1037
- High Pressure Decorative Laminates ANSI/NEMA LD3
- Specific Gravity ASTM D-792



PACKAGING:

- ISTA 1a, 1b, 1c, 1d, 1e, 1f, 1g, 1h, 2a, 2b, 2d, 2e, 3a, 3e, 3f, 3h, 5b, 7a to 7d
- Vibration (ASTM D 999, A1, A2)
- Drop (ASTM D 5276)
- Compression (ASTM D 642)
- Incline Impact (ASTM D 880)
- Temperature and humidity cycling
- Packaging design and optimization
- Accredited by the International Safe Transit Association (ISTA)
- Transport Canada recognized for Hazardous Materials Packaging Testing (UN boxes)
- Wal-Mart.com approved
- JC Penny approved



CLIMATE EXPOSURE:

- Climatic chambers (Humidity, temperature cycling)
- (-73°C à +150°C, 10 – 95% RH)
- Weatherometry, U.V. exposure (ASTM G 155)
- Salt spray (ASTM B-117)
- Accelerated temperature ageing
- Laboratory simulations of field failures
- Thermal shocks
- High and low temperature tensile and compression tests
- Long term exposure for stability studies

CORRUGATED BOARD:

- Burst (Mullen) (T 807,810)
- Construction
- Board Thickness (T 411)
- Pin Adhesion (T 821)
- Coefficient of Friction (T 815)
- Flat Crush (T 825)
- Score Quality Test (T 829)
- Manufacturer's Joint Tensile Test (T 813)
- Edge Crush Test (T 811)
- Water Absorption of Corrugated Medium
- Water Drop (T 835)
- Float Curl (T 832)
- Boat Method (T 819)
- Tensile Strength (T 494)
- Moisture Content at Equilibrium (T 412)
- Tear Resistance (T 414)
- Abrasion Taber (T 426)

OTHER SERVICES AND TESTS:

- Various flammability tests
- Computer data acquisition and control
- Custom testing
- Hazardous Products act, (lighters)
- Research and development
- Other ASTM test methods
- Scientific expertise and consulting services

