Health Canada’s Guidelines for Temperature Control of Drug Products during Storage and Transportation (Version 2)

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Presentation Outline

• General Overview of GUI-0069
• Sample Observations / Deviations
• Next Steps for GUI-0069
• Introduction
  • Section C.02.015 - Food and Drug Regulations
  • Transported, handled and stored in manner that mitigates risk of exposure…
  • Temperature excursions outside of labelled storage conditions, for brief periods, may be acceptable provided stability data and scientific/technical justification exist demonstrating that drug product quality is not affected.
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• Scope
  • All persons and companies involved in storage and transportation of drug products.
  • Health Canada’s jurisdiction (F/P/T/I/D/W)
  • Written agreements between regulated parties and transportation providers
  • Human, veterinary, clinical trial products and samples
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• Definitions
  • Carriers / Transportation Providers
  • Controlled Storage Conditions
  • Final Distribution Point
  • Stability Data
  • Lane/Route Profile
  • Qualified Shipping Package/Container
  • Temperature Excursion
Warehousing and Storage
- Storage conditions (temperature, humidity, light, etc.)
- Temperature monitoring – sensors located at worst case scenarios of Refrigerators and Freezers
- Procedure of action in the case of temperature excursion from the set parameters
- Training of personnel
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- Product Transportation and Products in Transit
  - Flexibility for shipping outside of label conditions for brief periods (stability and scientific justification needed)
  - Transport process and containers prevent damage and maintain quality of drug
  - Shipping procedures should be established and qualified;
  - Controlled storage conditions during transit (environmental controls must be in place)
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• Product Transportation and Products in Transit
  • Refrigerated vehicles and containers should be mapped and monitored if primary means of environmental control
    • Not necessary if qualified container, etc.
  • Temperature / humidity monitoring devices calibrated at predetermined intervals.
  • Transportation practices by carriers, including any storage and/or transportation activities performed by sub-contractors, should be periodically verified by reviewing documentation.
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- Containers and Container Labelling
  - Controlled transport / storage conditions / warning statements should be clearly stated on label
  - Shipping containers should be qualified
  - Warm/cold packs
  - Dry ice (Transportation of Dangerous Goods Act)
  - Temperature monitoring devices and product disposition after an excursion
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• Receiving
  • Receiving bays should protect deliveries from inclement weather and be separate from storage area
  • Temperature sensitive drugs should be examined upon reception and results recorded
  • Products should be promptly transferred to environmentally controlled storage area
  • Controlled substances and narcotics
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• Documentation
  • Written agreement between regulated party and carriers
  • Maintain transportation records of inbound and outbound shipments
  • Records of investigations and actions taken after excursions
  • Temperature monitoring data and alarm records (includes maintenance and calibration records for monitoring equipment)
Sample Observations
Sample Observations

Risk / Risque : 2 (Repeat Observation)
Quality control department - C.02.015

The firm’s written transportation procedures detailing shipping processes for temperature sensitive drugs did not clearly outline the following:

i) container types and sizes,

ii) warm/cold packs type, size, and storage temperature,

iii) barrier materials type and size,

iv) specific packaging configurations,

v) maximum shipping durations, and

vi) details of the storage conditions provided by the carriers selected for distribution.
Sample Observations

Risk / Risque : 3
Quality control department
The shipping of finished product did not include a requirement to ship temperature sensitive products at labelled conditions. (Eg. Heated service in winter months if product susceptible to freezing)
There was no evidence that responsibilities for ensuring acceptable transport conditions would be included in quality contractual agreements.
Sample Observations

Risk: 2 (Repeat Observation)
Quality control department - C.02.015

The SOP on transportation was general in scope and did not detail the specific procedures to be followed, when using air/land carriers, to meet the labelled temperature conditions of;

- Temperature sensitive products (2-8 degrees Celsius)
- Products requiring ambient storage conditions (15-25; 15-30 degrees Celsius).
Sample Observations

Risk: 2 (Repeat Observation)
Quality control department - C.02.015

There was no evidence that outgoing transportation conditions would not negatively affect the quality of drug products. (Examples: Temperature controlled transport conditions were not used for cold winter days or hot summer days. No stability data provided to support not using temperature controlled conditions. No evidence of periodic temperature monitoring of shipments on route from the distributor to the customer was documented.)
Sample Observations

Risk: 2
Quality control department - C.02.015

- Evaluation of the actual transportation conditions considering seasonal variations had not been performed to ensure that products were maintained according to their labelled storage conditions. Additionally, the estimated maximum length of time required for transportation of the drugs, including any in transit storage had not been evaluated.

- The written quality agreements describing the respective responsibilities of the parties involved in the maintenance of the chain storage, transportation conditions, returned products, recalls, etc. between the company and the wholesalers were not all available.
7 Most Common Compliance Issues

- Temperature monitoring
- Temperature mapping in warehouses/storage areas
- Quality agreements
- Training of personnel
- Improper temperature range for selected device
- No assurance of product quality
- Procedures lacking significant elements
Next Steps for GUI-0069 Version 2

• Respond to all comments received
• Summary of changes
• Post revised version of Guide
  • Forecast for Fall 2010
  • Implementation 3-6 months after final version posted
Thank you!

Questions by e-mail:

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