



Guidelines for environmental control of drugs during storage and transportation



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Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

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Disclaimer

This document does not constitute part of the *Food and Drugs Act* (the Act) or its regulations and in the event of any inconsistency or conflict between the Act or regulations and this document, the Act or the regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the regulations and the applicable administrative policies.

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The following are the three types of icons used in this document, and the way they are intended to be used.



Important: Key or cautionary information for people to know.



Information: Supplementary information like quotes and legal references.



Tip: Things to do or understand.

About this document

1. Purpose

These guidelines apply to all persons (individuals and companies) involved in the storage and transportation of drugs. It will help those who store and/or transport drugs to comply with Canada's [Food and Drugs Act](#) (the Act) in accordance with C.02.015 of the [Food and Drug Regulations](#) (the Regulations). It is the responsibility of each person to ensure that the required storage and transportation conditions are met throughout the supply chain.

This includes:

- fabricators
- packagers/labellers
- testers
- distributors
- importers
- wholesalers



You are required to comply with Good Manufacturing Practices (GMPs) and this guidance if you are providing contract storage and transportation services (referred to as contract acceptor). Drug Establishment Licence (DEL) holders (the contract giver) are ultimately responsible for ensuring all contract acceptors meet these requirements.

2. Scope

These guidelines apply if you or your company are involved in storing or transporting the following drugs:

- drugs for human use
- drugs for veterinary use
- clinical trial drugs for human use (as required by C.05.010(j))
- samples of drugs distributed to professionals (as outlined in Sections C.01.048 and C.01.049 of the Regulations)



These guidelines do not include the following:

- Blood and blood components for transfusion or for use in the manufacture of a drug for human use. For requirements relating to blood and blood components (for transfusion or for use in the manufacture of a drug for human use), please see [Guidance Document: Blood Regulations](#).
- Cells, Tissues and Organs (please see [Guidance Document for Cell, Tissue and Organ Establishments - Safety of Human Cells, Tissues and Organs for Transplantation](#)).
- Sperm and ova for assisted reproduction.

3. Introduction

These guidelines interpret the requirements for Good Manufacturing Practices (GMP) in Part C, Division 2 of the Regulations. They were developed by Health Canada in consultation with stakeholders.

Guidance documents like this one are meant to help industry and health care professionals understand how to comply with regulations. They also provide guidance to Health Canada staff, so that the rules are enforced in a fair, consistent and effective way across Canada.

Health Canada inspects establishments to assess their compliance with the Act and associated regulations. When conducting an inspection, Health Canada will use this document as a guide in assessing your compliance with GMP requirements.

These guidelines are not the only way GMP regulations can be interpreted, and are not intended to cover every possible case. Other ways of complying with GMP regulations will be considered with proper scientific justification. Also, as new technologies emerge, different approaches may be called for. This document builds on other international guidance (see [References](#)).

Guidance documents are administrative and do not have the force of law. Because of this, they allow for flexibility in approach. Use this guide to help you develop specific approaches that meet your unique needs.

Guidance

4. Principles

To preserve drug safety, quality and efficacy, proper storage and transportation conditions must be maintained throughout the drug supply chain. This ranges from the point of manufacture to the delivery of products to the final distribution point, normally the person who dispenses or provides drugs to the patient. Planning for the drug supply chain should begin with product development phases and continue through the product lifecycle.



If you or your company are a distributor, importer, wholesaler, fabricator, packager/labeller or tester, you must meet the drug storage and transportation conditions that are approved by the person in charge of the quality control department for your operations, pursuant to Section C.02.015 of the Food and Drug Regulations.



You must also comply with Section 11 of the [Act](#), which prohibits storing for sale any drug under “unsanitary conditions”, defined in Section 2 of the Act as meaning “such conditions or circumstances as might contaminate with dirt or filth, or render injurious to health...a drug”.

4.1 The role of environmental controls

Environmental controls are essential to maintaining drug safety, quality and efficacy. Drugs must be stored and transported according to labelled storage conditions or specific transport conditions supported by data.



Temperature is one of the most important parameters to control. You must transport, handle and store drugs in a way that reduces the risk of exposure to temperatures outside the labelled storage conditions—also known as “temperature excursions”.

Temperature excursions may be acceptable for brief periods if stability data and scientific or technical justification show that product quality is not affected.

In addition to temperature, storage conditions limiting humidity, exposure to light, or limits to physical stress may occasionally be stated on the label. Measures need to be taken during storage and transport to abide by these required conditions. This document includes primarily temperature related guidance and examples, but the same principles should be applied when controlling other environmental conditions.

4.2 About Quality Risk Management (QRM)

The supply chain parties should maintain a quality system setting out responsibilities, processes and QRM principles in relation to their activities. QRM should ensure that the evaluation of the risk to quality is based on scientific knowledge, experience with the process and ultimately links to the protection of the patient. The level of effort, formality and documentation of the process should be commensurate with the level of risk. Examples of the processes and applications of quality risk management can be found in [*International Council for Harmonisation \(ICH\) Q9: Quality Risk Management*](#). The above is taken from [*PIC/S Guide to Good Distribution Practice \(GDP\) for Medicinal Products \(PE 011-1\)*](#). You may also refer to [*PIC/S Guidelines on GDP of Active Substances for Human Use \(PI 047-1\)*](#), which has a similar statement on use of QRM.

4.3 Special considerations for Active Pharmaceutical Ingredients (API)

This guide can help you understand how you can comply with storage and transportation requirements for APIs. Keep in mind that expectations will depend on the properties of the API, how it is packaged and how it is labelled (some APIs may not be labelled with storage conditions). You can apply this guidance as appropriate based on your knowledge of the API and application of QRM principles. API manufacturers are required to have stability documentation in place to support recommended storage conditions. For further

information, see [\(ICH\) Q7 Good manufacturing practice guide for active pharmaceutical ingredients](#). Expectations harmonized with ICH are also described in [Good Manufacturing Practices \(GMP\) Guidelines for Active Pharmaceutical Ingredients \(API\) - \(GUI-0104\)](#). ICH Q7 specifies obligations for warehousing procedures and distribution procedures requiring you to:

- store all material under appropriate conditions
- transport APIs and intermediates in a manner that does not adversely affect their quality
- state special transport or storage conditions for an API or intermediate on the label
- ensure that the contract acceptor (contractor) for transportation of the API or intermediate knows and follows the appropriate transport and storage conditions

5. Interpretation

5.1 Warehousing and storage

1. Store all drugs according to the conditions described on the label of the product. Ensure any controls for conditions that are specified on the label (e.g. temperature, humidity, light, etc.) are in place. Each building used to store drugs must be indicated on your DEL warehouse annex. Furthermore, when using contracted third parties to store drugs, it is your responsibility to ensure that the buildings used to store the drugs are indicated on your DEL warehouse annex and that contracted third parties store the drugs according to the conditions described on the label. For more information on DEL requirements including the storage of drugs please refer to [Guidance on Drug Establishment Licences \(GUI-0002\)](#).
2. Design or adapt storage areas to ensure good conditions. Make sure they are clean and dry, with enough air circulation. Ensure they are kept within all acceptable temperature limits and ensure they are qualified (see [Guide to validation – drugs and supporting activities \(GUI-0029\)](#) for more information). To reduce human error, general storage areas should be well lit.
3. Monitor the area to demonstrate storage conditions indicated on the label are being met and keep a record of your findings (refer to [Section 5.5 Documentation](#)). Use calibrated monitoring devices to control and monitor temperatures.



For more information, please refer to [U.S. Pharmacopeia: General Chapters: <659> Packaging and Storage Requirements](#) and [<1079> Good Storage and Distribution Practices for Drug Products](#).

4. Keep temperature monitoring records and notes of any alarms. Monitor the locations in your storage facility where temperatures are most likely to deviate from the required temperature range (i.e. worst-case locations). Identify those areas through temperature mapping, and ensure you are monitoring at the most appropriate locations.
5. Make sure any refrigerators and freezers you use to store drugs:
 - are of appropriate design and capability
 - are qualified (see [Guide to validation – drugs and supporting activities \(GUI-0029\)](#) for more information)
 - are maintained in a good state of repair
 - are equipped with alarms for temperature excursion notifications
 - are free from excessive frost build-up
 - consist of a two-door unit with a separate freezer compartment and door (when freezer and refrigerator are combined)
 - allow for enough air circulation and orderly storage within the chamber in accordance with loading patterns verified during qualification (storage practices and loading configurations should not obstruct air circulation)
 - have sensors (calibrated according to the calibration program) for continuous monitoring in locations where temperatures are most likely to deviate from the required range
 - are equipped with a backup power source when the refrigerator or freezer is deemed to be critical (or else you may have a backup plan in the event of a failure)
6. Considerations in qualification of refrigerators and freezers include:
 - temperature mapping to assess temperature distribution using empty and full loads
 - door open challenges to assess how long the door can be kept open without exceeding temperature limits or recovery time after door opening
 - power loss challenges to assess how long temperature ranges can be held during a power failure
 - alarm challenges to verify set-points and functionality

- sufficient duration in studies to capture compressor and defrost cycles
- ambient load challenges or cool down verification to assess the time it takes to achieve set temperatures after being loaded with higher temperature goods representing typical loads



The WHO has a series of guidance documents supporting many of the topics discussed here. The series of documents is listed at [Introduction to the Technical Supplements, WHO Technical Support Series No. 961, 2011](#). One of these documents offers suggested approaches to qualification of fridges and freezers in particular at [Supplement 7 TS-Qualification of temperature-controlled storage areas](#).

7. Document all your storage procedures in writing and describe the actions that should be taken in the event of temperature excursions. All excursions must be investigated and any decision to retain or dispose of affected stock must be based on evidence such as stability data, with technical justification. It may be necessary to consult with the Market Authorization Holder (MAH) regarding the effect of the excursion.
8. Define the roles of personnel involved in storing and warehousing drugs, and provide appropriate training at predetermined intervals based on your company's needs. Make sure your training program provides information on training needs, practices and how training effectiveness will be evaluated. Keep records of the training that is delivered.
9. You may use Mean Kinetic Temperature (MKT) in monitoring only if the use is in accordance with that of a recognized pharmacopoeia specified in [Schedule B](#) of the Act. There should be a procedure outlining when the use of MKT is appropriate and a methodology to determine which calculations will be made.



The use of MKT may not be appropriate in cases where:

- liquids or suspensions are subject to phase change
- products require refrigeration or freezing
- products are biologics
- data may indicate that temperature excursions have an impact on product quality

5.2 Product transportation

1. Make sure all necessary environmental controls are in place when specific

storage conditions (such as temperature, relative humidity and lighting) are required for products in transit.

2. Establish written procedures for the transportation of drugs. Drugs should be transported in a way that ensures products will be maintained within an acceptable temperature range as described by the approved labelling.
3. All shipping conditions must be in accordance with label requirements unless there is appropriate justification to allow brief excursions (i.e. during shipping).
4. This justification should be in accordance with QRM principles and should include the following:
 - you have a clear understanding of the shipping route and mode and the extremes of environmental conditions to which the product could be exposed.
 - stability data exists to address the planned excursion and evaluates the worst case in terms of frequency and severity of excursions potentially encountered throughout the distribution chain. As mentioned previously, this information is also useful in assessing the effects of unplanned excursions. Consider whether studies such as freeze/thaw and high temperature cycling should be performed.



The early exposure to the extreme temperatures in freeze/thaw and high temperature cycling studies should be evaluated for potential to affect stability at end of shelf life. The considerations for extension of the studies may include, whether:

- any significant change was observed during [*ICH Q1A – Stability testing of new drug substances and products*](#) accelerated storage conditions
- any new degradants were formed
- the assay or potency of the drug product has changed
- there have been any phase related changes

5. MAHs and importers/distributors are expected to have all such information available to justify shipping conditions. Wholesalers and other parties in the distribution chain may rely on information and instructions provided by the other licensed parties.
6. Ensure the procedures account for the nature of the drugs, expected climatic conditions (local, national, international), modes of transport, potential

transportation delays and any seasonal variations. Describe any special handling precautions.

7. Ensure your transport process and containers are designed to prevent damage and maintain the integrity and quality of the drugs. For example, transport conditions for ampoules should limit their exposure to physical stress to avoid the development of hairline cracks which may result in contamination and loss of sterility.
8. Include in your written procedures any contingency plans for unforeseen delays that could occur during shipping and transportation. For example, these might include delays caused by security inspections or equipment malfunctions. Ensure your plans provide contact information for personnel who are available to respond outside of normal business hours.
9. Temperature-map and monitor any temperature controlled vehicles or transportation containers (such as air cargo containers with external power supply) that actively provide the primary means of environmental control. Temperature mapping determines the appropriate placement of temperature-controlling and monitoring devices. However, this may not be necessary if a qualified insulated container/package, or an appropriate temperature monitoring device on the package or selected packages, or gel packs or similar approved means, or lane profile data are used as the primary means of environmental control.
10. Calibrate any devices that monitor temperature and humidity (such as data loggers) at predetermined intervals. Check temperature and humidity monitoring devices periodically to ensure they are working within established limits. Ensure that any single-use monitoring devices are qualified (for example, verify the accurate performance of indicator strips or freeze indicator units).



For certain exceptions to this requirement, see [Section 5.5 Documentation](#) of this guide.

11. Make sure drugs are transported in accordance with the established procedures. When using contracted third parties, it is your responsibility to ensure that they transport the drugs within the established procedures.
12. Review and verify your carriers' transportation practices as well as those of any contracted third parties involved in storage or transportation. Verify and confirm all

parties agree to ship drugs within the established procedures. Keep a record of your review and follow up on any discrepancies you find (refer to [Section 5.5 Documentation](#) for written agreements with commercial carriers including subcontractors).

13. Make sure all vehicles and equipment used to distribute, store or handle drugs are suitable for their use and protect the drugs appropriately—for example, that they prevent contamination of any kind as well as exposure to conditions that could affect their stability or packaging integrity.
14. Ensure loading and unloading activities preserve the quality of the drugs.
15. You may use MKT in monitoring only if the use is in accordance with that of a recognized pharmacopoeia specified in [Schedule B](#) to the Act. There should be a procedure outlining when the use of MKT is appropriate and a methodology to determine which calculations will be made. Please refer to [Section 5.1.9 Warehouse and Storage](#) for appropriate use of MKT.

5.3 Containers and container labelling

Containers for shipping can be as simple as the outer carton or cardboard box used to facilitate movement of the bulk unit through the distribution chain. It also provides basic protection from handling. Additional packaging components and systems can be used, where required, to maintain the required temperature, sometimes referred to as an insulated/thermal container or ‘pack out’. The choice of container will depend on the temperature requirements of the product and the mode of transportation to be used.

1. Ensure any necessary labels about transport, storage conditions or warnings are applied to the outside of shipping containers or cartons (for example, “Time and temperature sensitive” or “Do not freeze”). Make sure labels are printed in indelible ink and are applied securely. The label and shipping documents should clearly state that these products should be transferred without delay to the specified storage temperature upon receipt.
2. Make sure labels are written in the relevant language(s) for transport to ensure handlers understand the requirements.
3. Qualify thermal shipping containers/pack-out to meet the required temperature conditions during expected extremes of ambient temperature if they provide the main means of environmental control for the drug.



Base your choice of a thermal shipping container or box on the:

- storage and transportation requirements of the drugs
- space needed for the volume of drugs being transported
- expected extremes of ambient temperature based on lane/route profiling
- estimated maximum time needed to transport the drugs including any in-transit storage

You should periodically check that changes have not occurred on the transport route that may affect the expected temperatures to which containers are exposed. You should consider seasonal extremes in this monitoring.

4. Make sure the procedures for placing warm or cold packs in containers to transport drugs address the following:
 - the type, size and number of packs correspond to the shipping time and temperature requirements
 - the location of the packs will maintain the specified storage conditions for the entire volume of product within the shipping container
 - enough barrier materials are used to prevent contact between packs and products; if the packs are at a temperature outside the range acceptable for product storage, there should be clear procedural controls outlining their conditioning and placement
5. Make sure any dry ice used when transporting drugs does not adversely affect the drug, the primary package, or label.



Handle dry ice according to the [*Transportation of Dangerous Goods Act*](#), or applicable provincial legislation.

6. Use temperature monitoring devices or temperature indicators when needed. If a thermal shipping container has been qualified, ongoing monitoring may not be necessary provided it is confirmed periodically. However, the need for ongoing monitoring should be risk managed (e.g. temperature sensitive drugs may warrant ongoing monitoring).
7. If temperature excursions occur, assess and document them to determine whether or not to accept or reject the product. Take and document any

corrective action. Provide clear directions so the recipient can evaluate monitoring devices/indicators and determine if products should be accepted or rejected.

5.4 Receiving

Receiving is an important role that may occur several times and in different locations along the distribution chain, including storage warehouses and the final distribution point.

1. Ensure receiving bays protect deliveries from poor weather during unloading. Receiving and storage areas should be separate.
2. Follow written procedures upon shipment arrival. Check that containers are not damaged and the shipment matches the order. Where specific conditions (e.g. temperature, relative humidity, light) are required during transit, you should examine the shipment on arrival and ensure the conditions have been met. Record the results.
3. Transfer products promptly to the proper environmentally-controlled storage area.
4. Excursions or damaged shipments must be investigated and communicated to the person (usually the MAH) having sufficient information to make a decision to accept or reject affected stock. Such decisions must be based on evidence. The investigation should involve all relevant parties in the distribution chain, so corrective action can be taken by the appropriate party.



Immediately identify and store controlled drugs and substances that are subject to security measures according to written instructions and legal requirements. Monitor and maintain security on these products at the legally required level. For more information, see [Controlled Substances and Precursor Chemicals](#).

If upon receipt and examination you suspect a drug may be falsified, diverted or counterfeit refer to [Policy on Counterfeit Health Products \(POL-0048\)](#).

5.5 Documentation

1. When contracted parties such as warehouses or commercial carriers store or transport drugs, outline all relevant conditions in a written agreement with the service provider or contract acceptor. The contract acceptor must follow the written agreement, which at a minimum should include:
 - a provision for responsible parties to audit and monitor contractor performance at any time
 - transportation and storage requirements for the products and materials
 - where applicable, an obligation to report any excursions or deviations back to the person best positioned to make a quality assessment
 - a requirement to notify the contract giver of any proposed subcontracting



Arrangements made between the contract acceptor and any third party should ensure that the information is shared and made available in the same way as between the original contract giver and contract acceptor. [PIC/S Guide to Good Distribution Practice for Medicinal Products \(PE 011-1\)](#).

2. In addition to keeping records of the examination of the shipment (i.e. a receiving record), there should also be a record of any temperature monitoring.
3. Maintain calibration and maintenance records for monitoring equipment.
4. Maintain records associated with storage and transportation, including excursion investigations one year after the expiry date of the product, unless stated otherwise on your DEL.
5. Note that records retention requirements for APIs can be found in [Good Manufacturing Practices \(GMP\) Guidelines for Active Pharmaceutical Ingredients \(API\) - \(GUI-0104\)](#).



You may be requested to provide records of pre- and post-calibration of devices used for temperature mapping if you use devices such as thermocouples.

You may use QRM to determine whether pre- and post-calibration is required for more stable or rugged devices like thermistors, since these are not often subject to temperature drift.

Appendices

Appendix A – Glossary

Acronyms

API:	Active pharmaceutical ingredient
DEL:	Drug establishment licence
GDP:	Good distribution practices
GMP:	Good manufacturing practices
ICH:	International Council for Harmonisation
MAH:	Market authorization holder
MKT:	Mean kinetic temperature
PIC/S:	Pharmaceutical Inspection Cooperation Scheme
QRM:	Quality risk management

Terms



The following definitions apply to the terms used in these guidelines. They supplement the definitions provided in the [*Good manufacturing practices guide for drug products \(GUI-0001\)*](#).

Active ingredient – “A drug that, when used as a raw material in the fabrication of a drug in dosage form, provides its intended effect.” (C.01A.001(1))

Active pharmaceutical ingredient – “An active ingredient that is used in the fabrication of a pharmaceutical.” (C.01A.001(1))

Drug – Includes any substance or mixture of substances manufactured, sold or represented for use in:

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoring, correcting or modifying organic functions in human beings or animals, or
- (c) disinfection in premises in which food is manufactured, prepared or kept

(Section 2 of the *Food and Drugs Act*)

From Part C, Division 1A of the Food and Drug Regulations;

(2) In this Division and in Division 2, drug does not include any of the following:

(a) a dilute drug premix;

(b) a medicated feed as defined in subsection 2(1) of the Feeds Regulations, 1983;

(c) an active ingredient that is for veterinary use and that is not an active pharmaceutical ingredient;

(d) an active pharmaceutical ingredient for veterinary use that is not required to be sold pursuant to a prescription and that is also a natural health product as defined in subsection 1(1) of the Natural Health Products Regulations;

(e) a drug that is used only for the purposes of an experimental study in accordance with a certificate issued under section C.08.015.

Final distribution point – The final destination where the drug will be dispensed or provided to the patient (for example: pharmacy, hospitals, clinics, retail stores).

Lane/route profile – The temperature data collected on a product that is outside of a temperature protective shipping package, used to get a sample of the environmental conditions along the transportation routes used for shipping the product.

Mean kinetic temperature – The single calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures. (*United States Pharmacopeia: General Chapters: <1079> Good Storage and Distribution Practices For Drug Products and United States Pharmacopeia: General Chapters: <659> Packaging and Storage Requirements*).

Qualification – The action of proving and documenting that equipment or ancillary systems are properly installed, work correctly and actually lead to the expected results.

Qualified shipping container/package – A package that can repeatedly demonstrate (through documented testing) a high degree of assurance that the determined acceptance criteria are met and that it will maintain the quality of the drug under such conditions.

Temperature excursion – A variance in temperature outside of labelled storage conditions.

Appendix B – References

Laws and regulations

[Food and Drug Regulations](#)

laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/index.html

[Food and Drugs Act](#)

laws-lois.justice.gc.ca/eng/acts/f-27/

[Transportation of Dangerous Goods Act](#)

laws-lois.justice.gc.ca/eng/acts/T-19.01/

Health Canada guidance documents

[Controlled Substances and Precursor chemicals](#)

<https://www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals.html>

[Good manufacturing practices guide \(GUI-0001\)](#)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/good-manufacturing-practices-guidelines-2009-edition-version-2-0001.html>

[Good Manufacturing Practices \(GMP\) Guidelines for Active Pharmaceutical Ingredients \(API\) - \(GUI-0104\)](#)

www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/drugs/guidelines-active-pharmaceutical-ingredients-0104.html

[Guidance on Drug Establishment Licences \(GUI-0002\)](#)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/directives-guidance-documents-policies/guidance-drug-establishment-licences-drug-establishment-licensing-fees-0002.html>

[Guidance Document: Blood Regulations](#)

www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/blood-regulations/guidance-document-blood-regulations.html

[Guidance Document for Cell, Tissue and Organ Establishments – Safety of Human Cells, Tissues and Organs for Transplantation](#)

www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/regulatory-initiatives/cells-tissues-organs/guidance-document-safety-human-cells-tissues-organs-transplantation.html

[Policy on Counterfeit Health Products \(POL-0048\)](#)

www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/activities/policy-counterfeit-health-products-0048.html

[Guide to validation – drugs and supporting activities \(GUI-0029\)](#)

www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/validation/validation-guidelines-pharmaceutical-dosage-forms-0029.html

International guidance documents

[ICH Q1A: Stability Testing of New Drug Substances and Products](#)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/international-conference-harmonisation/quality/stability-testing-new-drug-substances-products-topic.html>

[ICH Q7: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients](#)

https://database.ich.org/sites/default/files/Q7_Guideline.pdf

[ICH Q9: Quality Risk Management](#)

www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/international-conference-harmonisation/quality/adoption-international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-use.html

[PIC/S Guideline on Good Distribution Practice \(GDP\) for Active Substances \(PI 047-1\)](#)

www.picscheme.org/en/publications?tri=all

[PIC/S Guideline to Good Distribution Practice \(GDP\) for Medicinal Products \(PE 011-1\)](#)

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[United States Pharmacopeia: General Chapters: <659> Packaging and Storage Requirements](#)

www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/659_rb_notice_english.pdf

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<https://www.usp.org/>

[World Health Organization: Introduction to the Technical Supplements, WHO Technical Support](#)

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[World Health Organization: Supplement 7 TS-Qualification of temperature-controlled storage areas](#)

www.who.int/biologicals/expert_committee/Supplement-7-TS-qualification-storage-areas-ECSP-ECBS.pdf

Other related documents

[Canada Communicable Disease Report, National Guidelines for Vaccine Storage and Transportation](#)

publications.gc.ca/collections/Collection/H12-21-21-11E.pdf

[European Medicines Agency: Guidelines on Good Distribution Practice of Medicinal Products for Human Use](#)

ec.europa.eu/health/human-use_en

[International Air Transport Association Perishable cargo regulations](#)

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[Parenteral Drug Association: Guidance for Temperature-Controlled Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment \(TR 37, 2007\)](#)

www.pda.org/bookstore/product-detail/1154-tr-39-guidance-for-temperature-controlled-medicina

[Parenteral Drug Association: Guidance for Industry: Stability Testing to Support Distribution of New Drug Products \(TR 53, 2011\)](#)

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[World Health Organization: Good Distribution Practices \(GDP\) For Pharmaceutical Products](#)

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