



Our Mandate:

The Inspectorate's mandate is to manage and deliver a national compliance and enforcement program for blood and donor semen; cells, tissues and organs; drugs (human and veterinary); medical devices and natural health products, collaborating with and across, all regions.

Health Products and Food Branch Inspectorate

Guidance Document Alternate Sample Retention Site Guidelines

GUI-0014

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Disclaimer:

This document does not constitute part of the Food and Drugs Act (Act) or its associated Regulations and in the event of any inconsistency or conflict between that 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. This document is not intended to provide legal advice regarding the interpretation of the Act or Regulations. If a regulated party has questions about their legal obligations or responsibilities under the Act or Regulations, they should seek the advice of legal counsel.

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1.0 Purpose

These guidelines are designed to facilitate compliance to Section C.02.025 of the [Food and Drug Regulations](http://laws.justice.gc.ca/eng/regulations/C.R.C.,_c._870/index.html) (http://laws.justice.gc.ca/eng/regulations/C.R.C.,_c._870/index.html) and to enhance consistency in the application of the regulatory requirements by describing the requirements regarding Alternate Sample Retention (ASR) sites for finished drug products.

2.0 Background

The Good Manufacturing Practices (GMP) *regulations* contain the following requirement:
C.02.025

- (1) Every distributor referred to in paragraph C.01A.003(b) and importer of a drug shall retain in Canada a sample of each lot or batch of the packaged/labelled drug for a period of at least one year after the expiration date on the label of the drug unless otherwise specified in the distributor's or importer's establishment licence.

This requirement helps to assure access to samples of finished drug products should a quality concern arise.

On a product specific basis, consideration for an ASR site will be given upon a written request with appropriate justification.

3.0 Scope

The guidelines apply to distributors and importers of pharmaceutical, radiopharmaceutical, biological and veterinary drugs intending to store retention samples outside of Canada.

4.0 Guide

4.1 Criteria for assessment

The Health Products and Food Branch Inspectorate (HPFBI) will give consideration for ASR for the products that meet one or more of the following criteria:

- The drug is subject to testing under Health Canada's lot release program (for example: lot release Group 2 or 3) as outlined in the document entitled "Guidance for Sponsors - Lot Release Program for Schedule D (Biologic) Drugs". (http://www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/lot/gui_sponsors-dir_promoteurs_lot_program-eng.php)
- There is a limited volume of the drug sold in Canada or small portions of many batches.
- Individual samples of the drug are very expensive. The total number of samples of complete batches to be retained (for example, high volume) is not a consideration.
- The drug product is a radiopharmaceutical.
- Category IV monograph drugs as specified in the Health Canada guideline entitled Annex 1 to the Current Edition of the "Good Manufacturing Practices Guidelines - Selected Category IV

Monograph Drugs (GUI-0066)” (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/gui-0066_annex_1-eng.php)

- The drug product is a hard surface disinfectant.
- The fabricator of the drug is located in Canada.

4.2 Requirements for storage of samples at sites located outside of Canada

To support use of an ASR site, the applicant must provide:

- Evidence of GMP compliance for the foreign site that meets the requirements described in Health Canada’s document entitled “Guidance on Evidence to Demonstrate Drug GMP Compliance of Foreign Sites (GUI-0080)”. (<http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/gui-0080-eng.php>).
- Evidence that sufficient numbers of samples of lots sold in Canada will be maintained to allow access to those samples by Health Canada.
- A commitment to provide samples within 48 hours of receiving a request from Health Canada.

4.3 Application process

Applicants requesting use of an ASR Site must complete the form entitled “Alternate Sample Retention Site Application Form” (Appendix A). Completed forms along with supporting evidence described in section 4.2 should be submitted to the Establishment Licence Unit.

This product specific request should be submitted annually with a Drug Establishment Licence (DEL) application, amendment, notification, or renewal.

If the application criteria are met, then an ASR Site Annex will accompany the DEL. The ASR Site Annex must accompany the documents submitted for the Annual Review of the DEL.

If the ASR Site application does not pass the screening criteria, a letter of refusal will be sent to the applicant.

Should circumstances change regarding any of the information submitted, the applicant must immediately inform the Establishment Licence Unit.

Appendix A

Alternate Sample Retention (ASR) Site Application Form

*Once completed, please mail, email or fax this application form to the Establishment licence Unit at:

Health Products and Food Branch Inspectorate

Establishment Licence Unit

250 Lanark Avenue

Address Locator 2002A

Ottawa, Ontario K1A 0K9

Fax: 613-957-4147

Email: DEL_questions_LEPPP@hc-sc.gc.ca

1. Importer or Distributor

Name: _____

Address: _____

Telephone number: _____

Fax number: _____

Email: _____

2. Product

Brand Name: _____

DIN (if applicable): _____

3. Alternate Sample Retention (ASR) Site where samples are to be retained

Name: _____

Address: _____

Telephone number: _____

Fax number: _____

4. Justification for use of ASR Site (Taking into consideration the criteria outlined in section 4.1 of the Alternate Sample Retention Site Guidelines (GUI-0014):

5. Confirmation

- A. We have formally arranged with the ASR site to maintain sufficient numbers of samples under approved storage conditions, with the container-closure authorized for sale in Canada.
- B. We have a written commitment with the responsible person at the ASR site that samples will be provided within 48 hours of receiving a request from Health Canada.
- C. We confirm that we will immediately notify Health Canada if the information contained in the form becomes inaccurate at any time during the year that the approval applies.

I hereby certify that all the information on this form is true, accurate and complete.

Name of Responsible Officer: _____

Signature of Responsible Officer: _____

Date: _____

Emergency Telephone Number: _____

The ASR Site Annex must accompany the documents submitted for the Annual Review of the DEL.