Health Canada
Health Products and Food Branch

OUR MANDATE:

To promote good nutrition and informed use of drugs, food, medical devices and natural health products, and to maximize the safety and efficacy of drugs, food, natural health products, medical devices, biologics and related biotechnology products in the Canadian marketplace and health system.

Health Products and Food Branch Inspectorate

Guideline

Validation Documentation Requirements and Responsibilities for Drug Fabricators, Packagers / Labellers, Distributors and Importers

Supersedes:
New

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July 10, 2001

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August 1, 2001

*Revisions were made to this document on 2002-03-25 to reflect changes to the Health Products and Food Branch organizational structure. There were no other changes made to the content of the document.

Ce document est aussi disponible en français.

Canada

SCOPE

This guidance has been prepared to specify what documented evidence the Health Products and Food Branch Inspectorate (HPFBI) considers acceptable during an inspection, from drug establishments, to demonstrate compliance with validation requirements. Parties responsible for validation activities are also identified.

INTRODUCTION

As specified in the Scope section of the *Validation Guidelines for Pharmaceutical Dosage Forms*, it is expected that importers and distributors of drugs have documented evidence, as outlined below, that the fabricators and packagers of these drugs meet the validation requirements. The availability of information respecting the validation is a shared responsibility between the fabricator and the distributor.

At the fabrication site, inspectors will evaluate the validation master plan, the qualification of systems and equipment and the validation of cleaning methods. In cases where the product specific process validation studies have not been submitted as part of a drug submission, assessment of process validation will be verified by the inspector.

INFORMATION REQUIRED

The following information should be available for the purpose of inspection and evaluation:

1. For distributors of drugs fabricated, packaged and tested in Canada:

1.1 a certificate of manufacture with a certificate of analysis or a fabricator's batch certificate

1.2 a copy of the fabricator's valid Establishment Licence

1.3 complete process validation information, on an individual product basis, when not available at the fabricator's site.

2. For importers of drugs fabricated, packaged and tested in countries having a signed Mutual Recognition Agreement (MRA) with Canada:

2.1 a fabricator's batch certificate

2.2 the valid importer's Establishment Licence identifying the foreign site.

3. For importers of drugs fabricated, packaged and tested in non-MRA Countries:

3.1 a certificate of manufacture with a certificate of analysis

3.2 the valid importer's Establishment Licence identifying the foreign site

3.3 product specific process validation documentation showing:

3.3.1 the validation approach utilized by the fabricator (prospective, concurrent or retrospective)

3.3.2 the reference numbers and dates of approval for:

- the master formula including packaging
- the process validation protocol
- the process validation studies
- the validation of the test methods

3.3.3 the lot numbers involved and the dates of completion of these studies

3.3.4. a certified copy of the approved conclusions of the product validation studies

Upon request, copies of complete protocols and related studies for all validation activities must be provided to the importer within 72 hours. These documents must not be sent directly to HPFB unless specifically requested to do so.

RESPONSIBILITIES:

4. For Canadian fabricators, packagers or testers of drugs:

4.1 validation master plan, cleaning validation and qualification of utilities, supports systems and equipment are the responsibility of the fabricator; these elements will be verified by the inspector at the fabricator's site;

4.2 for marketed drugs, when process validation data have not been submitted as part of a submission application, these data will be verified by the inspector at the fabricator's site.

5. For distributors of drugs fabricated, packaged and tested in Canada:

5.1 the inspector will verify, at the distributor's site, the availability and the completeness of the information referred to in Section 1

6. For importers of drugs from MRA Countries:

6.1 the inspector will verify, at the importer's site, the availability and the completeness of the information referred to in Section 2

7. For importers of drugs from non-MRA Countries:

7.1 for marketed drugs, the inspector will verify, at the importer's site, the availability and the completeness of the information referred to in Section 3.

8. For all drug establishments:

8.1 for new drugs, the relevant evaluation units within the Therapeutic Products Directorate (TPD) or Biologics and Genetic Therapies Directorate (BGTD) will evaluate the process validation specific to the product