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International Harmonized Requirements for Batch Certification

Content of the Fabricator's / Manufacturer's Batch Certificate for Drug / Medicinal Products (*Content of the Batch Certificate for Medicinal Products*) Exported to Countries under the Scope of a Mutual Recognition Agreement (MRA)

NOTE: the following information supersedes the information available in Appendix 1 of GUI-0001.

Explanatory Note

In the framework of Mutual Recognition Agreements (MRA), the Sectoral Annex on Good Manufacturing Practices (GMP) requires a batch certification scheme for medicinal products covered by the pharmaceutical Annex. The internationally harmonized requirements for the content of the batch certificate of a medicinal product are provided in this document.

Each batch of medicinal product transferred between countries having appropriate arrangements on GMP, must be accompanied by a batch certificate issued by the manufacturer in the exporting country. In the framework of MRAs all manufacturing sites must be located in the country issuing the certificate or in another MRA country, if reciprocal arrangements are in force.

This certificate will be issued further to a full qualitative and quantitative analysis of all active and other relevant constituents to ensure that the quality of the products complies with the requirements of the marketing authorisation of the importing country. The batch certificate will attest that the batch meets the specifications and has been manufactured in accordance with the marketing authorisation of the importing country, detailing the specifications of the product, the analytical methods referenced, the analytical results obtained, and containing a statement that the batch processing, packaging and quality

control records were reviewed and found in conformity with GMP. The batch certificate will be signed by the person responsible for certifying that the batch is suitable for release for sale or supply/export at the manufacturing site.

The importer of the batch of medicinal product is to receive and maintain the batch certificate issued by the manufacturer. It has to be available to regulatory authorities of the importing country. This certification by the manufacturer on the conformity of each batch is essential to exempt the importer from re-testing.

Where applicable this batch certificate shall also be used for non-finished medicinal products such as intermediates, bulk or partially packed products.

This certificate may also be used for investigational medicinal products used in clinical trial authorisations.

These harmonized requirements have been agreed bilaterally by Canada with the regulatory authorities of the following countries: Australia, countries of the European Economic Area - European Free Trade Association (EEA-EFTA), Member States of the European Union (EU) and Switzerland.

Content of the Batch Certificate for Medicinal Products

[LETTER HEAD OF EXPORTING MANUFACTURER]

1. Name of product
2. Importing country
3. Marketing authorisation number or Clinical Trial Authorisation Number
4. Strength/Potency
5. Dosage form
6. Package size and type
7. Batch number
8. Date of manufacture
9. Expiry date
10. Name, address and authorisation number of all manufacturing sites and quality control sites
11. Certificates of GMP Compliance of all sites listed under 10 or, if available, EudraGMP reference numbers
12. Results of analysis
13. Comments/remarks
14. Certification statement
15. Name and position/title of person authorising the batch release
16. Signature of person authorising the batch release
17. Date of signature

Explanatory Notes and Glossary

1. Name of product

Proprietary, brand, trade or proper name in the importing country, as applicable. For

Investigational Medicinal Products (IMPs) the code number as referred to in the clinical trial application.

2. Importing Country

3. Marketing Authorisation Number or Clinical Trial Authorisation Number

The marketing authorisation number of the product in the importing country. For IMPs, the Clinical Trial authorisation number or trial reference to be provided when available.

4. Strength/Potency

Identity (name) and amount per unit dose required for all active ingredients/constituents.IMPs include placebos and the manner in which this information is provided should not unblind the study.

5. Dosage form or pharmaceutical form, e.g. tablets, capsules, ointments

6. Package size and type

This would be the contents of container and vials, bottles, blisters, etc.

7. Batch number

or Lot number related to the product. Unique combination of numbers, letters or symbols that identifies a batch and from which the production and distribution history can be determined.

8. Date of manufacture

In accordance with national (local) requirements of the importing country.

9. Expiry date

The date placed on the container/label of a product designating the time during which the product is expected to remain within the authorised shelf life specifications authorised by the importing country, if stored under defined conditions, and after which it should not be used.

10. Name, address and authorisation number of all manufacturing and quality control sites

All sites involved in the manufacture including packaging/labelling and quality control of the batch should be listed with name, address and authorisation number. The name and address must correspond to the information provided on the manufacturing authorisation.

11. Certificates of GMP Compliance of all sites listed under 10 or, if available, EudraGMP reference numbers

Certificate numbers and/or EudraGMP reference numbers should be listed under this item.

12. Results of analysis

Should include the authorised specifications, all results obtained and refer to the methods used (may refer to a separate certificate of analysis which must be dated, signed and attached).

13. Comments/remarks

Any additional information that can be of value to the importer and/or inspector verifying the compliance of the batch certificate (e.g. specific storage or transportation conditions).

14. Certification statement

This statement should cover the fabrication/manufacturing, including packaging/labelling and quality control. The following text should be used: "I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country or product specification file for Investigational Medicinal Products. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP".

15. Name and position/title of person authorising the batch release

Including the name and address, if more than one site is mentioned under item 10.

16. Signature of person authorising the batch release

17. Date of signature

Glossary of equivalent terms used in the Certificate template (non-exhaustive)

- batch = lot
- dosage form = pharmaceutical form
- manufacturer = fabricator
- manufacturing/manufacture = fabrication
- manufacturing authorisation = establishment licence
- medicinal product = pharmaceutical product = drug product
- quality control = testing

Date Modified: 2014-12-04

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