EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 June 2011
EMA/INS/MRA/387218/2011 Rev 5
Compliance and Inspection

Internationally harmonised requirements for batch certification

in the context of Mutual Recognition Agreements, Agreements on Conformity Assessment and Acceptance of Industrial Products and other appropriate arrangements on GMP with the European Union.

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Internationally Harmonised Requirements for Batch Certification

in the context of Mutual Recognition Agreements, Agreements on Conformity Assessment and Acceptance of Industrial Products and other appropriate arrangements on GMP with the European Union.

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. Batch certification is also required in the Agreements on Conformity Assessment and Acceptance of Industrial Products (ACAA) and other appropriate arrangements on GMP between third countries and the European Union (EU).

The internationally harmonised 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. In the framework of the European Union's ACAA with Israel (once in operation) all quality control sites must be located in Israel or the EU.

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.

The importer / site of batch release of the medicinal product is to receive and maintain the batch certificate issued by the manufacturer of the exporting country. Upon request, it has to be readily available to the staff of the regulatory authorities of the importing country. This certification by the manufacturer on the conformity of each batch is essential to exempt the importer / site of batch release from re-control (for the EU, see Directive 2001/83/EC Art. 51.2 and Directive 2001/82/EC Art. 55.2).

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 active pharmaceutical ingredients and investigational medicinal products used in clinical trial authorisations. The terminology may need to be adapted as per the *Glossary*.

These harmonised requirements have been agreed bilaterally by the European Union with the regulatory authorities of the following countries: Australia, Canada, Israel, Japan, New Zealand and Switzerland.

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Content of the Batch Certificate for Medicinal Products

(Note: For equivalence of terminology refer to the Explanatory Notes and Glossary)

[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
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

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Explanatory Notes and Glossary

1 Name of product

Proprietary, brand or 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 Certificate of GMP Compliance of all sites listed under 10 or, if available, EudraGMP reference number

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

Common Part

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

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

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EU Revision History

Adopted and published final version	1 February 2001
Revision 1 - only explanatory note	26 April 2002
Revision 2 - only explanatory note	22 October 2002
Revision 3 - only explanatory note	16 December 2002
Revision 4 - Draft 3 EU agreed, awaiting MRA partners comments	27 January 2004
Revision 4 – additions to include investigational medicinal products	1 May 2004
Revision 5 – editorial changes, extension of use of the certificate to other arrangements on GMP and addition of quality control sites was agreed; draft subject to comments of MRA/ACAA partners;	15 September 2010
Revision 5 – addition of a glossary and adoption by GMDP IWG	24 May 2011

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