MUTUAL RECOGNITION AGREEMENTS
Sectoral Annex on Good Manufacturing Practices

Final
Internationally Harmonised Requirements for Batch Certification

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Internationally Harmonised Requirements for Batch Certification

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

Explanatory Note

In the framework of Mutual Recognition Agreements, the Sectoral Annex on Good Manufacturing Practices (GMP) requires a batch certification scheme for drug/medicinal products covered by the pharmaceutical Annex. The internationally harmonised requirements for the content of the batch certificate of a drug/medicinal product is attached. The importer of the batch is to receive and maintain the batch certificate issued by the fabricator/manufacturer. Upon request, it has to be readily available to the staff of the Regulatory Authority of the importing country. This certification by the manufacturer on the conformity of each batch is essential to exempt the importer from re-control (re-analysis).

Each batch transferred between countries having an MRA in force, must be accompanied by a batch certificate issued by the fabricator/manufacturer in the exporting country. 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. This 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 and packaging quality control records were reviewed and found in conformity with GMP. The batch certificate will be signed by the person responsible for releasing the batch for sale or supply/export at the fabrication/manufacturing site.

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

These harmonised requirements have been agreed by the Regulatory Authorities of the following parties/countries: Australia, Canada, European Community, New Zealand and Switzerland.

Version 1 - 2001-02-01
Content of the Fabricator’s/Manufacturer’s Batch Certificate
for
Drug/Medicinal Products Exported to Countries
under the Scope of a Mutual Recognition Agreement (MRA)

[ LETTER HEAD OF EXPORTING MANUFACTURER]

1. Name of product.
   Proprietary, brand or trade name in the importing country.

2. Importing Country.

   The marketing authorisation number of the product in the importing country should be
   provided.

4. Strength/Potency.
   Identity (name) and amount per unit dose required for all active ingredients/constituents.

5. Dosage form (pharmaceutical form).

6. Package size (contents of container) and type (e.g. vials, bottles, blisters).

7. Lot/batch number.
   As related to the product.

8. Date of fabrication/manufacture.
   In accordance with national (local) requirements.

9. Expiry date.

10. Name and address of fabricator(s)/manufacturer(s) - manufacturing site(s).
    All sites involved in the manufacture including packaging and quality control of the batch
    should be listed with name and address. The name and address must correspond to the
    information provided on the Manufacturing Authorisation/Establishment Licence.

11. Number of Manufacturing Authorisation / Licence or Certificate of GMP Compliance of
    a manufacturer/fabricator.
    Number should be given for each site listed under item 10.

12. Results of analysis.
    Should include the authorized 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).

    This statement should cover the fabrication/manufacturing, including packaging 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 fabricated/manufactured, including
    packaging 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. The batch processing, packaging and analysis records
    were reviewed and found to be in compliance with GMP”.

15. Name and position/title of person authorizing the batch release.
    Including its company/site name and address, if more than one company is mentioned under
    item 10.

16. Signature of person authorizing the batch release.

17. Date of signature.