

# **Internationally Harmonised Requirements for Batch Certification**

## **Content of the Manufacturer's Batch Certificate for Veterinary Medicinal Products Exported to EU Countries under the 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 are attached. The importer of the batch is to receive and maintain the batch certificate issued by the 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 manufacturer in the exporting country. This certificate will be issued following 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 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.

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

[ LETTER HEAD OF EXPORTING MANUFACTURER]

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

- 1. Name of product.**  
Proprietary, brand or trade name in the importing country.
- 2. Importing Country.**
- 3. Marketing Authorisation Number.**  
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 manufacture .**  
In accordance with national (local) requirements.
- 9. Expiry date.**
- 10. Name and address of 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.**  
Number should be given for each site listed under item 10.
- 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 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 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 authorising the batch release.**

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

**16. Signature of person authorising the batch release.**

**17. Date of signature .**