

**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.**
- 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 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 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 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 authorising the batch release.**

Including its 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.**