**Manufacturers/official1 batch certificate of a pharmaceutical product**

This certificate conforms to the format recommended by the World Health Organization (general instructions and explanatory notes attached)

1. No. of Certificate:

2. Importing (requesting) authority:

3. Name of product:

3.1. Dosage form:

3.2 Active ingredient(s)2 and amount(s) per unit dose:

3.2.1 Is the composition of the product identical to that registered in the country of export? (yes/no/not applicable)3

If no: please attach formula (including excipients) of both products.

4. Product-licence holder4 (name and address):

4.1 Product-licence number4:

4.2 Date of issue4:

4.3 Product licence issued by4:

4.4 Product certificate number4,5:

5.1 Batch number:

5.2 Date of manufacture:

5.3 Shelf life (years):

5.4 Contents of container:

5.5 Nature of primary container:

5.6 Nature of secondary container/wrapping:

5.7 Specific storage conditions:

5.8 Temperature range:

6 Remarks6:

7. Quality analysis:

7.1 What specifications apply to this dosage form. Either specify the pharmacopoeia or append company specifications.7

7.1.1 In the case of a product registered in the exporting country, have these company specifications7 been accepted by the competent authority? (yes/no)

7.2 Does the batch comply with all parts of the above specifications? (yes/no)

7.3 Append certificate of analysis8

It is hereby certified that the above declarations are correct and that the results of the analyses and assays on which they are based will be provided on request to the competent authorities in both the importing and exporting countries.

Name and address of authorized person:

Telephone no:

Fax number:

Signature of authorized person:

Stamp and date:

**Explanatory notes**

Certification of individual batches of a pharmaceutical product is only undertaken exceptionally by the competent authority of the exporting country. Even then, it is rarely applied other than to vaccines, sera and biologicals. For other products, the responsibility for any requirement to provide batch certificates rests with the product-licence holder in the exporting country. The responsibility to forward certificates to the competent authority in the importing country is most conveniently assigned to the importing agent.

Any inquiries or complaints regarding a batch certificate should always be addressed to the competent authority in the exporting country. A copy should be sent to the product- licence holder.

* Strike out whichever does not apply.
* Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.
* "Not applicable" means that the product is not registered in the country of export.
* All items under 4 refer to the product licence or the Certificate of a Pharmaceutical Product issued in the exporting country.
* This refers to the Certificate of a Pharmaceutical Product as recommended by the World Health Organization.
* Indicate any special storage conditions recommended for the product as supplied.
* For each of the parameters to be measured, specifications give the values that have been accepted for batch release at the time of product registration.
* Identify and explain any discrepancies from specifications. Government batch release certificates issued by certain governmental authorities for specific biological products provide additional confirmation that a given batch has been released, without necessarily giving the results of testing. The latter are contained in the manufacturer's certificate of analysis.