Appendix 2

Model batch certificate of pharmaceutical products

Manufacturers/official[1] batch certificate of a pharmaceutical product

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

1. No. of certificate: _____

2. Importing (requesting) authority: _____

3. Name: (International Nonproprietary Name (INN)/generic/chemical name); brand name of the pharmaceutical product as it is declared in the marketing authorization certificate and, if possible, brand name for the foreign country, if different. _____

   _____

   _____

   3.1. Dosage form: _____

   3.2. Composition: Active pharmaceutical ingredient name(s) using, if possible, International Nonproprietary Names (INNs) or national nonproprietary names. Unit formulation (complete quantitative composition including all excipients): _____

   _____

   _____

   3.2.1 Is the composition of the product identical to that registered in the country of export? *Yes/No/Not applicable* (*key in as appropriate*)[2] _____

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

4. Marketing authorization holder[3] (name and address): _____

   _____

   _____

   4.1 Marketing authorization number[3]: _____

   4.2 Date of issue[3]: _____

   4.3 Marketing authorization issued by[3]: _____

4.4 Certificate of a pharmaceutical product (CPP) number[3,4]: _____

_____

5. Pharmaceutical product information:

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. Quality analysis: _____

_____

_____

6.1 What specifications apply to this dosage form? Either specify the pharmacopoeia or append company specifications.[5] _____

_____

6.1.1 In the case of a product registered by the certifying country or regional authority, have these company specifications[5] been accepted by the competent authority? Yes/No (*key in as appropriate*) _____

6.2 Does the batch comply with all parts of the above specifications? Yes/No (*key in as appropriate*) _____

6.3 Append certificate of analysis. Identify and explain any discrepancies from specifications.

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: _____

_____

_____

Validity of the certificate[6]: _____

Telephone number: _____ Website: _____

Email address: _____

Signature of authorized person: _____

Stamp and date (*electronic whenever possible*): _____

General instructions

Please refer to the guidelines for full instructions on how to complete this form and for information on the implementation of the Scheme.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

The certification of individual batches of a pharmaceutical product is only undertaken on an exceptional basis by the competent authority. Even then, it is rarely applied other than to biological products, such as vaccines, blood and plasma derivatives. For other products, the responsibility for any requirement to provide batch certificates rests with the marketing authorization holder in the certifying country or within the jurisdiction of the certifying regional authority. 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 certifying competent authority. A copy should also be sent to the marketing authorization holder.

[1] Strike out whichever does not apply.

[2] "Not applicable" means that the product is not registered in the country of export.

[3] All items under 4 refer to the marketing authorization or the certificate of a pharmaceutical product (CPP) issued in the certifying country or within the jurisdiction of the certifying regional authority.

[4] This refers to the CPP as recommended by WHO.

[5] 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.

[6] The validity of the certificate should not be confused with the expiry period of the batch/lot.