

# Appendix 1

## Model certificate of a pharmaceutical product

### Certificate of a pharmaceutical product

This certificate conforms to the format recommended by the World Health Organization (WHO). It establishes the status of the pharmaceutical product and of the applicant for the certificate by the national certifying authority in the country or within the jurisdiction of the regional certifying authority. It is for a single product only since the manufacturing arrangements and approved information for different dosage forms and different strengths can vary. (*General instructions and explanatory notes are attached.*)

No. of certificate: \_\_\_\_\_

Certifying country or regional certifying authority: \_\_\_\_\_

Requesting country(countries) or regional authority(authorities): \_\_\_\_\_

### 1. Basic information

1.1. Name: (International Nonproprietary Name (INN)/generic/chemical name); brand name of the pharmaceutical product as it is declared in the marketing authorization certificate and used within the territory of the certifying authority and, if possible, the brand name for the foreign country as declared by the requester, (if different); and, the dosage form of the finished pharmaceutical product (FPP): \_\_\_\_\_

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1.2. Composition: active pharmaceutical ingredient name(s) using if possible, INNs or national nonproprietary names,. Unit formulation (complete quantitative composition including all excipients);<sup>1</sup>: \_\_\_\_\_

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1.3. Is this product authorized by the certifying authority to be marketed in the certifying country or within the jurisdiction of the certifying regional authority? Yes/No (*key in as appropriate*).

1.3.1 Are there restrictions of the sale, distribution or administration of the product specified in the marketing authorization? Yes/No (*key in as appropriate*). See attached information if Yes.

1.4. Is this product actually on the market in the certifying country or within the jurisdiction of the certifying regional authority? Yes/No/Unknown (*key in as appropriate*).

Sections 2A and 2B below are mutually exclusive, therefore:

- If the answer to 1.3 above is yes, continue with section 2A and omit section 2B.
- If the answer to 1.3 above is no, omit section 2A and continue with section 2B

## 2. Information on marketing authorization

2.A. Product that is authorized for marketing by the certifying authority.

2.A.1. Number of marketing authorization and date of issue. (*Indicate, when applicable, if the marketing authorization is provisional and the marketing authorization pathway, e.g. abridged, etc*): \_\_\_\_\_

2.A.2 Marketing authorization holder (name and address): \_\_\_\_\_

2.A.3. Status of marketing authorization holder (*one of the options of 3.1, if manufacturer, or specify the status as importer or any other*): \_\_\_\_\_

2.A.4. Is a summary basis for approval appended? Yes/No (*key in as appropriate*). See attached information if answer is Yes.

2.A.5. Is the attached officially approved product information complete and consistent with the marketing authorization (*such as the Summary of Product Characteristics – SPC- or similar*)? Yes/No/Not provided (*key in as appropriate*). See attached information if answer is Yes.

2.A.6. Name and address of applicant for the certificate as provided by the marketing authorization holder, if different: \_\_\_\_\_

2.A.7. Web-link to the product marketing authorization information (if available) \_\_\_\_\_

2.B. Product that is not authorized for marketing by the certifying authority.

2.B.1. Applicant for certificate (name and address): \_\_\_\_\_

2.B.2. Why is marketing authorization lacking?  
Not required/Not requested/Under consideration/Refused/  
Withdrawal for commercial reasons/Withdrawal for sanitary  
reasons (*key in as appropriate*)

2.B.3. Reason provided by the applicant for not requesting registration.

(a) The product has been developed exclusively for the treatment of conditions (e.g. tropical diseases – not endemic in the exporting country): \_\_\_\_\_

(b) The product has been reformulated - please specify: \_\_\_\_\_

(c) Any other reason, please specify: \_\_\_\_\_

### 3. Information on manufacturing and inspections

3.1. List of name and address of the manufacturing site(s) and activities:

- a) manufacturing of all steps of the finished pharmaceutical product (FPP);
- b) manufacturing the bulk finished product;

- c) manufacturing of solvent and diluents;
- d) quality control of the FPP;
- e) batch release of the FPP;
- f) primary packaging of the dosage form;
- g) secondary packaging of the product;
- h) other(s) (specify and list in new arrows).

Name of manufacturing site	Address	Activity

- 3.2. Does the certifying authority arrange for periodic inspection of the manufacturing site in which the of the FPP is produced? Yes/No (*key in as appropriate*). If not, proceed to question 4.
- 3.3. Periodicity of routine inspections: \_\_\_\_\_
- 3.4. Has the manufacturer of the dosage form of the FPP been inspected? Yes/No (*key in as appropriate*). If Yes, when feasible, insert date of inspection(s) (*dd/mm/yyyy*).
- 3.5. Do the facilities and operations of the manufacturer of the FPP conform to good manufacturing practices (GMP) as recommended by WHO?<sup>2</sup> Yes/No (*key in as appropriate*).
- 3.6. It is recommended that for products approved, but not manufactured in the country of the certifying authority, the source of information that assures the GMP compliance of the manufacturer(es) is declared.
4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? Yes/No (*key in as appropriate*)<sup>3</sup>. If the answer is No, please explain: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Address of certifying authority: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Telephone number: \_\_\_\_\_ Website: \_\_\_\_\_

Email address: \_\_\_\_\_

Name and job title of authorized person: \_\_\_\_\_

Validity of the certificate<sup>4</sup> (optional): \_\_\_\_\_

Signature: \_\_\_\_\_

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

- <sup>1</sup> Details of quantitative composition are preferred but their provision is subject to the agreement of the marketing authorization holder.
- <sup>2</sup> The requirements for good practices in the manufacture and quality control of pharmaceutical products referred to in the certificate, are those included in the Thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series, No. 986, 2014, Annex 2 (*WHO Good manufacturing practices for pharmaceutical products: main principles*). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (*WHO Good manufacturing Practices for biological products*, WHO Technical Report Series, No. 996, 2016, Annex 3).
- <sup>3</sup> It is of particular importance when contractors are involved in the manufacture of the product. The applicant should supply the certifying authority with information in order to identify the contracting parties responsible for each stage of manufacture of the finished dosage form and the extent and nature of any controls exercised over each of these parties.
- <sup>4</sup> A period of validity can be provided by the authority on the certificate.