Invulinstructie WHO CPP certificaat

De voetnoten en algemene instructies van het certificaat kunnen behulpzaam zijn bij het invullen.

Item	Vul in
1.	naam (als deze afwijkend is van naam zoals geregistreerd in Nederland ook deze afwijkende benaming opgeven) en doseringsvorm (zie bijlage)
1.1	werkzame stof(fen): naam (INN) en hoeveelheid per doseringseenheid
1.2	eventuele (lopende) registratie in Nederland
1.3	eventuele beschikbaarheid op de Nederlandse markt
2A.1	RVG-nummer en datum van inschrijving
2A.2	naam en adres van registratiehouder
2A.3	status van de registratiehouder: a) fabrikant van de doseringsvorm b) verpakt en/of labelt de doseringsvorm gefabriceerd door een onafhankelijke fabrikant c) geen van bovenstaande mogelijkheden (o.a. als registratiehouder A/a-vergunninghouder)
2A.3.1	als b) of c) is ingevuld bij vraag 2A.3, dan ook naam en adres van alle bij het productieproces betrokken fabrikanten opgeven met vermelding van de uitgevoerde productiestappen (eventueel hoofdkantoor plus afzonderlijke productieplaats).
2A.4	(niet voor Nederlands geregistreerde producten; n.v.t.)
2A.5	als het product is geregistreerd moet een (vertaalde) 1B-tekst worden bijgevoegd, conform het registratiedossier
2A.6	als aanvrager van het certificaat niet de registratiehouder is, dan naam en adres van aanvrager invullen en schriftelijk toestemming van registratiehouder bijvoegen. Als hoofdkantoor en productieplaats fysiek gescheiden zijn, maar tot één concern behoren, dan naam en adres van beide apart vermelden
2B.1	naam en adres aanvrager van het certificaat
2B.2	zie 2A.3
2B.2.1	zie 2A.3.1.
2B.3	reden voor ontbreken van registratie
2B.4	eventuele toelichting op 2B.3
3.	ja of nee invullen als productieplaats/en in Nederland ligt/liggen; of als het product buiten de Europese Unie wordt geproduceerd; *niet van toepassing* invullen als productieplaats/en elders in Europese Unie ligt/liggen; of buiten de Europese Unie ligt/liggen en door een andere EU-lidstaat wordt (en) geïnspecteerd.
3.1	Voor Nederland: 3 jaar
3.2	zie laatste inspectiebrief
3.3	zie laatste inspectiebrief *niet van toepassing* invullen als productieplaats/en elders in Europese Unie of buiten de Europese Unie ligt.
4.	invullen: *ja* over productieplaatsen in Nederland heeft IGZ zelf informatie voorhanden; over productieplaatsen buiten Nederland moet voldoende informatie (vergunningen cq GMP-verklaringen) worden aangeleverd.

Ministry of HEALTH, WELFARE and SPORT
CIBG
P.O. Box 16114
2500 BC DEN HAAG
THE NETHERLANDS

Certificate of a Pharmaceutical Product[1]

This certificate conforms to the format recommended by the
World Health Organization.
(Explanatory Notes and General Instructions attached)

Exporting (certifying) country: The Netherlands No. of Certificate: .....

Importing (requesting) country:

1. Name and dosage form of product

.....

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3].
For complete composition including excipients see attached.
.....
.....
.....

1.2 Is this product licensed to be placed on the market for use in The Netherlands?[4]

(a) yes/no (b) application pending: yes/no

(key in as appropriate)

1.3 Is this product on the market in The Netherlands? yes/no/unknown (*key in as appropriate)*

If the answer to 1.2 (a) or 1.2 (b) is yes, continue with section 2A and omit section 2B;
If the answer to 1.2 (a) or 1.2 (b) is no, omit section 2A and continue with section 2B.[5]

2A.1 Number of product licence[6] and date of issue:
.....

2A.2 Product licence holder (name and address):

.....
.....
.....

2A.3 Status of product licence holder[7] : a/ b/ c/ *(key in appropriate category as defined in note 7)*

2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form is:[8]

(official company headquarters)	manufacturing plant(s)
(name)	*name*
(address)	*address*
(country)	*country*
	steps performed

.....

2A.4 Is summary basis of approval appended?[9] yes/no
(*key in as appropriate*)

2A.5 Is officially approved product information, complete and consonent with the licence, attached? yes/ no/ not provided [10] *(key in as appropriate)*

2A.6 Applicant for certificate, if different from licence holder (name and address)[11]:

.....

.....

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

.....

.....

2B.2 Status of applicant: a / b / c / *(key in appropriate category as defined in footnote 7)*

2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form is:[8]

.....

2B.3 Why is marketing authorization lacking?

not required/not requested/under consideration/refused
(key in as appropriate)

2B.4 Remarks[12] : .....

3. Does the Netherlands' certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?

yes/no/not applicable[13] *(key in as appropriate)*
If no, or not applicable proceed to question 4

3.1 Periodicity of routine inspections (years): 3

3.2 Has the manufacture of this type of dosage form been inspected?

yes/no *(key in as appropriate)*

3.3. Do the facilities and operations conform to GMP as recommended by the World Health Organization?[14]

yes/no/not applicable[13] *(key in as appropriate)*

4. Does the information submitted by the applicant satisfy the Netherlands' certifying authority on all aspects of the manufacture of the product[15].

yes/no *(key in as appropriate)* If no, explain:

.....
.....

Address of certifying authority: Ministry of Health, Welfare and Sport
CIBG
P.O. Box 16114
2500 BC Den Haag, The Netherlands
tel. : +31 70 340 6624

Name of authorized person:

.....

Signature:
.....

Stamp and date:
.....

This document is valid until 1 year after the date of issue. Unless one or more substantive changes take place within that period (e.g. the production location, the name or other information about the company stated on the CPP), as a result of which the issued CPP is no longer up to date for the goods that it's supplied with. In such situations, the manufacturer must submit a request for a new CPP.

General Instructions

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

2. The forms are suitable for generation by computer. They should always be submitted in type face.

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

Explanatory Notes

[1] This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
[2] Use, whenever possible, international nonproprietary names (INNs) or national nonproprietary names.

[3] The formula (complete composition) of the dosage form should be given on the certificate or be appended.

[4] When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is entered into the product licence.

[5] Sections 2A and 2B are mutually exclusive.

[6] Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.

[7] Specify whether the person responsible for placing the product on the market:

(a) manufactures the dosage form;
(b) packages and/or labels a dosage form manufactured by an independent company; or
(c) is involved in none of the above.

[8] This information can only be provided with the consent of the product licence holder or, in the case of non-registered products, the applicant. Non-completion of this section (2A.3.1) indicates that the party concerned has not agreed to inclusion of this information.

It should be noted that information concerning the site of production is part of the product licence. If the production site is changed, the licence has to be updated or it is no longer valid.

[9] This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.

[10] This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SPC)

[11] In this circumstance, permission for issuing the certificate is required from the product licence holder. This permission has to be provided to the authority by the applicant.

[12] Please indicate the reason that the applicant has provided for not requesting registration, e.g.:

a) the product has been developed exclusively for the treatment of conditions — particularly tropical diseases — not endemic in the country of export.
b) the product has been reformulated with a view to improving its stability under tropical conditions.
c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import.
d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient.
e) any other reason, please specify.

[13] Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

[14] The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the report of the Thirty-second Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No. 823, 1992. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization and are published in the WHO Technical Report Series.

[15] This section is to be completed when the product licence holder or applicant conforms to status (b) or (c) as described in note 7 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information 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.