**CERTIFICATE OF PHARMACEUTICAL PRODUCT1**

**CERTIFIKÁT PRO LÉČIVÝ PŘÍPRAVEK1**

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

Tento certifikát odpovídá formátu doporučenému Světovou zdravotnickou organizací (WHO) (obecné pokyny
a vysvětlivky uvedeny v příloze).

**Certificate No.:** Klikněte nebo klepněte sem a zadejte text.

Číslo certifikátu:

**Exporting (certifying) country:** Zvolte položku.

Vyvážející země (vydávající certifikát):

**Importing (requesting) country:** Klikněte nebo klepněte sem a zadejte text.

Dovážející země (požadující certifikát):

1. Name and dosage form of product:

 Název a léková forma přípravku:

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| Klikněte nebo klepněte sem a zadejte text. |

1.1. Active ingredient(s)2 and amount(s) per unit dose3:

 Účinné látky2 a jejich obsah v jedné dávce3:

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For complete composition including excipients see attached4.

Kompletní složení včetně pomocných látek viz. příloha4.

1.2. Is this product licensed to be placed on the market for use in the exporting country?5

 Je přípravek registrován ve vyvážející zemi?5

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| Zvolte položku. |

1.3. Is this product actually on the market in the exporting country?

 Je přípravek v současné době v oběhu ve vyvážející zemi?

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| Zvolte položku. |

If the answer to 1.2. is YES, continue with section 2A and omit section 2B. If the answer to 1.2. is NO, omit section 2A and continue with section 2B.6

Pokud je odpověď 1.2. ANO, pokračujete částí 2A a vynecháte část 2B. Pokud je odpověď NE, vynecháte část 2A a pokračujete částí 2B.6

2A.1. Number of product licence7 and date of issue:

 Registrační číslo7 a datum udělení registrace:

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| **RČ****Datum registrace** |

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

 Držitel rozhodnutí o registraci (jméno/název, adresa):

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| Zvolte položku. |

2A.3. Status of product licence holder:8

 Status držitele rozhodnutí o registraci:8

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| Klikněte nebo klepněte sem a zadejte text. |

2A.3.1. For categories b and c the name and address of the manufacturer producing the dosage form is:9

 Jméno (název) a adresa výrobce lékové formy (pouze u kategorií b a c odstavce 2A.3.):9

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| Zvolte položku. |

2A.4. Is summary basis of approval appended?10

 Je přiložena veřejná hodnotící zpráva?10

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| Zvolte položku. |

2A.5. Is the attached, officially approved product information complete and consonent with the licence?11

 Je přiložený oficiálně schválený souhrn údajů o přípravku kompletní a shodný s registrací?11

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| Zvolte položku. |

2A.6. Applicant for certificate, if different from licence holder (name and address):12

 Jméno a adresa žadatele o certifikát, pokud se liší od držitele rozhodnutí o registraci:12

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| Zvolte položku. |

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

 Žadatel o vydání certifikátu (jméno/název, adresa):

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| Zvolte položku. |

2B.2. Status of applicant:8

 Status žadatele o vydání certifikátu:8

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| Zvolte položku. |

2B.2.1. For categories b and c the name and address of the manufacturer producing the dosage form is:9

 Jméno (název) a adresa výrobce lékové formy (pouze u kategorií b a c odstavce 2B.2.):9

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| Zvolte položku. |

2B.3. Why is marketing authorization lacking?

 Proč chybí registrace?

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| Zvolte položku. |

2B.4. Remarks:13

 Poznámky:13

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

Provádí příslušný orgán, který vydává certifikát, pravidelné inspekce výrobního závodu, kde je daná léková forma vyráběna?

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| Zvolte položku. |

If no, or not applicable proceed to question 4.

Pokud je odpověď „ne“, nebo „není relevantní“, pokračujte částí 4.

3.1. Periodicity of routine inspections (years):

 Četnost pravidelných inspekcí (roky):

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| Zvolte položku. |

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

 Byla provedena inspekce výroby tohoto typu lékové formy?

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| Zvolte položku. |

3.3. Do the facilities and operations conform to GMP as recommended by the World Health Organization?15

Odpovídají zařízení a postupy zásadám správné výrobní praxe (GMS), doporučeným Světovou zdravotnickou organizací?15

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| Zvolte položku. |

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?16

Jsou informace předložené žadatelem pro příslušný orgán vydávající certifikát dostatečné ve všech aspektech výroby přípravku?16

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| Zvolte položku. |

If no, explain:

Pokud ne, vysvětlete:

 Jiří Bureš, D. V. M.

 Director of ÚSKVBL

 MVDr. Jiří Bureš

 ředitel ÚSKVBL

**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 Details of quantitative composition are preferred but their provision is subject to the agreement of the product licence holder.

5 When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.

6 Sections 2A and 2B are mutually exclusive.

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

8 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.

9 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 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.

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

11 This refers to product information approved by the competent national regulatory authority, such

as Summary Product Characteristics (SPC).

12 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.

13 Please indicate the reason that the applicant has provided for not requesting registration.

(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.

14 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.

15 The requirements for good practices in the manufacture and quality control of drugs 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. 823, 1992, Annex 1. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).

16 This section is to be completed when the product licence holder or applicant conforms to status (b) or (c)

as described in note 8 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.