No. of certificate: 417/21

BẢN SAO - COPY

CHIEF PHARMACEUTICAL INSPECTOR

CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

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

Exporting (certifying) country: **POLAND**

Importing (requesting) country: **VIETNAM**

1. Name and dosage form of the product:

Trade name and dosage form in Poland is: Amikacin Kabi, Solution for Infusion

Trade name and dosage form in Vietnam is: Amikacin Kabi, Solution for Infusion

1.1 Active ingredient(s)[2] and amount(s) per unit dose[3]:

Active Ingredient(s)	Amount(s) per unit dose
Amikacin	**5 mg/ml**

For complete composition including excipients, see attached. [4]
Excipients: sodium chloride, sodium hydroxide, hydrochloric acid, water for injections

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

☑ Yes ☐ No

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

☑ Yes ☐ No

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]

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fax 22 831 02 44

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2A.1. Number of product licence[7] and date of issue and expiry date:

- 25995
- 28.08.2020
- 28.08.2025

2A.2. Product licence holder:

Name: Fresenius Kabi Polska Sp. z o.o.
Address: Al. Jerozolimskie 134
02-305 Warszawa

2A.3. Status of the product licence holder [8]: (Key in appropriate category as defined in note 8)

☐ a ☐ b ☑ c

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

Address of the manufacturing site: Fresenius Kabi Polska Sp. z o. o.
ul. Sienkiewicza 25
99-300 Kutno
Poland

2A.4. Is a summary basis for approval appended[10] ?

☐ Yes ☑ No

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

☑ Yes ☐ No ☐ Not provided

2A.6. Applicant for certificate, if different from licence holder [12]:

Name: -
Address: -

Section 2 B is not included because the product named in this certificate is licensed in Poland [6]

3 Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? [14]

☑ Yes ☐ No ☐ Not applicable

IF NOT OR NOT APPLICABLE, PROCEED TO QUESTION 4

3.1. Periodicity of routine inspections (years): 3 years

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

☑ Yes ☐ No

3.3. Do the facilities and operations conform to GMP as recommended by the World Health Organization? [15, 14]

☑ Yes ☐ No ☐ Not applicable

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

☑ Yes ☐ No

If no, explain:-

Address of certifying authority:

Chief Pharmaceutical Inspector, 12 Senatorska Street, 00-082 Warsaw, Poland

Telephone: +4822 831 21 31
Fax: +4822 831 02 44

Name of authorized person: Ewa Krajewska

On the Chief Pharmaceutical Inspector authority

Signature:

Marcin Wójtowicz
Director General

Stamp and Date:

2021 -07- 05

LEGALIZACJA

Nr **46032/2021**

Ministerstwo Spraw Zagranicznych

poświadcza autentyczność podpisu

Marcin Wójtowicz

Główny Inspektor Farmaceutyczny

oraz tożsamość pieczęci urzędowej

Warszawa, dnia **2021-08-23**

Zbigniew Augustyn

Referat ds. Legalizacji

DEPARTAMENT KONSULARNY

MINISTERSTWO SPRAW ZAGRANICZNYCH * 12 *

CHỨNG THỰC BẢN SAO ĐÚNG VỚI BẢN CHÍNH

NGÀY: 06 -09- 2021

1838 - - - - - 02

Số chứng thực.....Quyển số.....SCT/BS

S.Đ.K.H.Đ: 94 - C.T.H.Đ

VĂN PHÒNG CÔNG CHỨNG HOÀNG BÍCH DIỆP

CÔNG CHỨNG VIÊN

Nguyễn Văn Tâm

CHỨNG NHẬN/ HỢP PHÁP HÓA LÃNH SỰ

1.Quốc gia:**Việt Nam**

Giấy tờ, tài liệu này

2.Chứng thực chữ ký của Ông/ Bà: **Zbigniew Augustyn**

3.Chức danh: Chuyên viên

4. Và con dấu của cơ quan: **Bộ Ngoại Giao Ba Lan**

được chứng nhận/hợp pháp hóa lãnh sự

5.Tại: **Lãnh sự Đại sứ quán**

6. Ngày 1 tháng 9 năm 2021

7.Cơ quan cấp: **Đại sứ quán nước CHXHCN Việt Nam tại CH Ba Lan**

8, Số: 1028 /LS-ĐSQ

KT. Đại sứ/

Tham tán

Nguyễn Minh Quế

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.

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Composition of the Drug Product (Amikacin 5 mg/mL, Solution for Infusion)

Table 1. Composition of the Proprietary Medicinal Product per 100 mL

Name of ingredients	Content	Function
Amikacin (base) corresponding to Amikacin Sulfate	0.500 g 0.668 g	active ingredient
Sodium Chloride	0.9 g	tonicity agent
Sodium Hydroxide (Corresponding to Sodium Hydroxide 5 M solution)	0 – 0.018 g (0-92.4 µL)	pH adjustment
optional		
Hydrochloric Acid (Corresponding to Hydrochloric acid concentrated)	0 – 0.018 g (0-40.5 µL)	pH adjustment
Water for Injections	94 – 100 g (94-100 mL)	solvent

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