(Form No.19)

**MINISTRY OF HEALTH, LABOUR AND WELFARE**

**GOVERNMENT OF JAPAN**

**2-2, KASUMIGASEKI 1-CHOME, CHIYODA-KU, TOKYO 100-8916**

**Certificate of a Pharmaceutical Product 1**

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

Certificate No.: Exporting Country：Japan

Importing Country：

1. Name and dosage form of Product：

1.1 Active ingredient(s) 2 and amount(s) per unit dose 3 (complete quantitative

composition including excipients is preferred)：See Attachments 4

1.2 Is this product licensed［approved and licensed］to be placed on the market

for use in the exporting country? 5

□yes - See Block A 6

□no - See Block B 6

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

□yes　　□no　　□unknown (key in as appropriate)

－A－

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| 2A.1 Number of product licence 7 and date of issue［marketing approval number and date］：  No.：  Date： |
| 2A.2 Product licence holder［marketing approval holder］(name and address)：  Name：  Address： |
| 2A.3 Status of product licence holder［marketing approval holder］： 8  □a　　□b　　□c (key in appropriate category as defined in note 8) |
| 2A.3.1 For categories b and c the name and address of the manufacturer producing  the dosage form are： 9  Name：  Address： |
| 2A.4 Is summary Basis of Approval appended? 10  □yes 　　□no (key in as appropriate) |
| 2A.5 Is the attached product information complete and consonant with the licence ［approval］? 11  □yes　　□no　　□not provided (key in as appropriate) |
| 2A.6 Applicant for certificate, if different from licence holder [marketing approval  holder](name and address)： 12  Name：  Address： |

－B－

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| --- |
| 2B.1 Applicant for certificate(name and address)：  Name：  Address： |
| 2B.2 Status of applicant：  □a　　□b　　□c (key in appropriate category as defined in note 8) |
| 2B.2.1 For categories b and c the name and address of the manufacturer producing the  dosage form are： 9  Name：  Address： |
| 2B.3 Why is marketing authorization lacking?  □not required □not requested  □under consideration □refused (key in as appropriate) |
| 2B.4 Remarks: 13 |

3. Does the certifying authority arrange for periodic inspection of the manufacturing

plant in which the dosage form is produced?

□yes □no　　□not applicable 14 (key in as appropriate)

If no or not applicable proceed to question 4.

3.1 Periodicity of routine inspection(years)：　　　 years

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? 15

□yes □no　　□not applicable(key in as appropriate)

4. Does the information submitted by the applicant satisfy the certifying authority on

all aspects of the manufacture of the product？ 16

□yes □no (key in as appropriate)

If no, explain：

Address of certifying authority： Pharmaceutical Safety Bureau,

Ministry of Health, Labour and Welfare

2-2, Kasumigaseki 1-chome,

Chiyoda-ku

Tokyo 100-8916

Pharmaceutical Evaluation Division（Medical Device Evaluation Division）

Telephone： +81-3-3595-2431 （+81-3-3595-2419）

Fax： 　+81-3-3597-9535 （+81-3-3597-0332）

Name of authorized person: （医薬品審査管理課長（医療機器審査管理課長）の氏名）

Director,（担当課の名称）

Signature：

Stamp and Date：General instructions

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

The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten. 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. Details of quantitative composition are preferred, but their provision is subject to the agreement of the product licence holder［approval and manufacturing 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［approval］.

6. Section 2A and 2B are mutually exclusive.

7. Indicate, when applicable, if the licence［approval］ 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 forms；

　(b) packages and/or labels a dosage forms manufactured by an independent company；or

　(c) is involved in none of the above.

9. This information can be provided only with the consent of the product licence holder

［approval and manufacturing 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 must be updated or it will cease to be 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［approved and licensed］.

11. This refers to the package insert which is used in the exporting country at the date of certification, as informed to Director General of WHO as the special reservation.

12. In this circumstance, permission for issuing the certificate is required from the product licence holder［approval and manufacturing licence holder］. This permission must 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 that 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 report of the thirty second 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［approval and manufacturing 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.