Daiichi-Sankyo

DAIICHI SANKYO CO., LTD.
Post-Marketing Regulatory Affairs Department
3-5-1, Nihonbashi Honcho, Chuo-ku,
Tokyo 103-8426, Japan
TEL: +81- 3-6225-1030 FAX: +81-3-6225-1917

September 13, 2016

Declaration

I, Toshifumi Akiba, hereby solemnly and sincerely declare that the attached document, "Certificate", is a genuine original.

And I make this declaration conscientiously with confidence in contents of the same to be true and correct.

Declared at Tokyo, Japan
this 13th day of September, 2016

Sincerely yours,

Toshifumi Akiba
Vice President
Post-Marketing Regulatory Affairs Department
DAIICHI SANKYO CO., LTD.

NOTARIAL CERTIFICATE

This is to certify that Rie Miyauchi, agent of Toshifumi Akiba, Vice President, Post-Marketing Regulatory Affairs Department of Daiichi Sankyo Co., Ltd., and authorized to sign to the attached document on behalf of the said corporation which is organized and existing according to the laws of Japan, located at 3-5-1, Nihonbashi Honcho, Chuo-ku, Tokyo, Japan, has stated in my very presence that said Toshifumi Akiba acknowledged himself to have signed to the attached document.

Dated this 13th day of September, 2016

ICHIRO SHINJO
Notary
2-2-6 , Ginza , Chuo-ku , Tokyo , Japan
Tokyo Legal Affairs Bureau

平成２８年登簿第　2029　号

認　　証

この　宣言書　の署名者　第一三共株式会社　薬制部　部長　秋　葉　敏　文　の

代理人　宮　内　理　江　は、本職の面前で本人がこの署名を自認する旨陳述した。

よって、これを認証する。

平成２８年　9　月　13　日、本公証人役場において

東京都中央区銀座２丁目２番６号　銀座公証役場

東　京　法　務　局　所　属

公　証　人

Notary

ICHIRO　SHINJO

証　　明

上記署名は、東京法務局所属公証人の署名に相違ないものであり、かつ、その押印は、真実のものであることを証明する。

平成２８年　9　月　13　日

東　京　法　務　局　長　　佐　藤　主　税

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country:　JAPAN
   This public document
2. has been signed by　ICHIRO　SHINJO
3. acting in the capacity of Notary of the Tokyo Legal Affairs Bureau
4. bears the seal/stamp of　ICHIRO　SHINJO , Notary

Certified

5. at Tokyo
6. September 13, 2016
7. by the Ministry of Foreign Affairs
8. 16-№ 043773
9. Seal/stamp:
10. Signature

A. Ogawa

Ayako OGAWA

For the Minister for Foreign Affairs

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.: 5922

Exporting Country : Japan

Importing Country : Republic of Chile

1. Name and dosage form of Product : TRANSAMIN TABLET, Tablets

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—

2A.1	Number of product licence [7] and date of issue [marketing approval number and date] : No. : 15300AMZ01211000 Date : December 20, 1978
2A.2	Product licence holder [marketing approval holder] (name and address) : Name : DAIICHI SANKYO CO., LTD. Address : 3-5-1, Nihonbashi Honcho, Chuo-ku, Tokyo, Japan
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 : CMIC CMO Co., Ltd. Shizuoka Plant Address : 1-588, Kanaya-azuma, Shimada, Shizuoka, Japan
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 :

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) : 2 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 and Environmental Health Bureau,
Ministry of Health, Labour and Welfare
2-2, Kasumigaseki 1-chome,
Chiyoda-ku
Tokyo 100-8916

Evaluation and Licensing Division
Telephone : +81-3-3595-2431
Fax : +81-3-3597-9535

Name of authorised person: Masanobu Yamada
Director, Evaluation and Licensing Division

Signature : M. Yamada
Stamp and Date : MAR. - 2. 2016

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 summarises 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.

Attachment

Per one tablet (573.6 mg)

JP	Tranexamic Acid	500 mg
JP	Carmellose Calcium	30 mg
JPE	Partially Hydrolyzed Polyvinyl Alcohol	20 mg
JP	Magnesium Stearate	10 mg
JP	Hypromellose	8.17 mg
JP	Macrogol 6000	1.63 mg
JP	Talc	2.98 mg
JP	Titanium Oxide	0.817 mg
JPE	Polydimethylsiloxane・Silicon Dioxide Mixture	0.0204 mg
JP	Carnauba Wax	minute amount

JP: The Japanese Pharmacopoeia
JPE: Japanese Pharmaceutical Excipients