Mẫu số 15b

MINISTRY OF HEALTH VIETNAM

Certificate No:

DRUG ADMINISTRATION

Certificate of a Pharmaceutical Product

Exporting (certifying) country: Viet Nam

Importing (requesting)country:

(This certificate conforms to the format recommended by the World Health Organization)

Proprietary Names (if applicable) and dosage form*:*

Active Ingredient (s) and amount (s) per unit dose:

1.Is this product licensed to be placed on the market for use in the exporting country? If yes, complete Box A, if no, complete Box B.

A. Product licence holder:

Address:

Tel:

Status of licence holder:

Number of product licence and date of issue:

Date: Date of review:

The name and address of manufacturer producing the dosage form:

Address:

Tel:

Is an approved technical summary appended? yes no

Is the attached product information complete and consonant with the licence?

yes no not provided

Applicant for certificate if different from the licence holder:

B

Applicant for certificate:

Status of applicant:

Why is authorization lacking?

not required not requested under consideration refused

Remarks

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

no If no, proceed to question 3

Periodicity of routine inspection (years): At least once every two years

Has the manufacturer of this type of dosage form been inspected: yes no

Do the facilities and operations conforms GMP as recommend by the World Health Organization? yes no

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3.Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product undertaken by another party?

yes no if no, explain:

Address of the certifying authority:

Ministry of Health Vietnam

Drug Administration

138A - Giang Vo - Ha Noi - Viet Nam

Name of authorized person:

Signature:

Stamp and date:

Nguồn: Thông tư 47/2010/TT-BYT