Mẫu số 15b

MINISTRY OF HEALTH VIETNAM

Certificate No:

DRUG ADMINISTRATION

Certificate of a Pharmaceutical Product

Exporting (certifying) country: Viet Nam

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

Importing (requesting)country:

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 ☐

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 ☐

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: