United States Food and Drug Administration

Center for Drug Evaluation and Research (CDER)
10903 New Hampshire Avenue, Silver Spring, MD 20993, USA
Email: CDERExportCertificateProgram@fda.hhs.gov Telephone: (301) 796-4950

Certificate of a Pharmaceutical Product

Certificate Issue Date:
Certificate No.

Certificate Expiration Date:
Exporting Country:
Importing Country:

1. International or National Nonproprietary Name (if applicable) and dosage form: **XXXXXXXXX (Active Pharmaceutical Ingredient)**
1.1 Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): **See Attachments**
1.2 Is this product **licensed** to be placed on the market for use in the exporting country?
1.3 Is this product actually on the market in the exporting country?

A	B
2A.1 Number of product-license and date of issue:	2B.1 Applicant for certificate (name and address)
2A.2 Product-license holder:	2B.2 Status of Applicant:
2A.3 Status of product-license holder:	2B.3 Why is authorization lacking? **not required** **not applicable** **under consideration** **refused** **XXXX**
2A.4 Is an approved summary basis appended?	2A.3.1 or 2B.2.1 Manufacturer name and address:
2A.5 Is the attached product information complete and consonant with the license?	2B.4 Remarks: **The firm proposes to export raw materials listed above, which, when properly labeled with statement "Caution: For manufacturing, processing or repacking", may be freely marketed in the United States of America at this time.**
2A.6 Applicant for certificate if different from the license holder (name and address):	

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?
3.1 Periodicity of routine inspection (years): **Pursuant to Section 510(h)(3) of the Federal Food, Drug, & Cosmetic Act, inspections will occur in accordance with a risk-based schedule.**
3.2 Has the manufacture of this type of dosage form been inspected:
3.3 Do the facilities and operations conform to GMP as recommended by the WHO? (GMP including 21 CFR Parts 210, 211 or ICH Q7A) **Yes, at time of inspection, site complies with U.S. CGMP**
4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product undertaken by another party?

This certificate conforms to the format recommended by the World Health Organization format revised 10[illegible]nt

Director
Imports Exports Compliance Branch
Division of Imports, Exports and Recalls
Office of Drug Security, Integrity & Response
Center for Drug Evaluation and [illegible]