

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- Foreign Manufacture

Certificate Issue Date: XXXXXXXX
 Certificate No. XXXXXXXXXXXX

Certificate Expiration Date: XXXXXX
 Exporting Country: United States of America
 Importing Country: XXXXXX

1. International or National Nonproprietary Name (if applicable) and dosage form:
 1.1 Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred):
 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?

Trade name (generic name) dosage and potency
 See Attachments
 Yes - See Block A
 Yes

A

B

2A.1 Number of product-license and date of issue: XXXXXXXXXX	2B.1 Applicant for certificate (name and address)				
2A.2 Product-license holder: XXXXXXXXXXXX	2B.2 Status of Applicant:				
2A.3 Status of product-license holder: XXXXXXXXXXXXXXXXXXXX	2B.3 Why is authorization lacking? <table style="width: 100%; border: none;"> <tr> <td style="text-align: center;">not required</td> <td style="text-align: center;">not applicable</td> <td style="text-align: center;">under consideration</td> <td style="text-align: center;">refused</td> </tr> </table>	not required	not applicable	under consideration	refused
not required	not applicable	under consideration	refused		
2A.4 Is an approved summary basis appended? No	2A.3.1 or 2B.2.1 Manufacturer name and address: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX				
2A.5 Is the attached product information complete and consonant with the license? Yes	2B.4 Remarks: <div style="background-color: black; width: 100%; height: 40px;"></div>				
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? Yes
 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? Yes
 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? Yes

This certificate conforms to the format recommended by the World Health Organization (WHO) 1997. Website: www.who.int

Huascar Batista, Chief
 Drug Imports and Exports Compliance Branch
 Office of Drug Security, Integrity & Recalls

