United States Food and Drug Administration
Certificate of a Pharmaceutical Product

Certificate No.
Conforms to WHO format revised 10/1/97

Exporting Country: United States of America
Importing Country: Taiwan

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): SEE ATTACHMENTS
1.2 Is this product licensed to be placed on the market for use in the exporting country? NO – See Block B
1.3 Is this product actually on the market in the exporting country? Yes

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: Neither
2A.3 Status of product-license holder:	2B.3 Why is authorization lacking? not required: XXXX; not applicable; under construction; refused
2A.4 Is an approved summary basis appended? No	2B.3.1 or 2B.2.1 Mfr:
2A.5 Is the attached product information complete and consonant with the license? No	Remarks: The firm proposes to export raw materials listed above, which, when properly labeled with statement "Caution: For further 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):	Manufactured and Packaged by: 49001 USA

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**

Address of certifying authority: **U.S. Food and Drug Administration**
10903 New Hampshire Avenue
Silver Spring, MD 20993, USA
Telephone: (301) 796-3120 Fax (301) 847-8742

Drug Imports and Exports Compliance Branch
Office of Drug Secur[redacted] Recalls
Office of Compl[redacted]
Center for Dr[redacted]

State of Maryland Sworn and subscribed to before me this 22nd day of October 2013.

[redacted]

NOTARY PUBLIC
PRINCE GEORGE'S COUNTY
MARYLAND