

# **United States Food and Drug Administration**

**Center for Drug Evaluation and Research**

**10903 New Hampshire Ave, Silver Spring, MD 20993, United States of America**

**CDERExportCertificateProgram@fda.hhs.gov - Telephone (301) 796-4950**

## **Certificate of a Pharmaceutical Product - Foreign Manufacturer**

Certificate Number **A1BC-2D3E**

Certificate Issue Date: **June 14, 2021**

Certificate Expiration Date: **June 13, 2023**

Importing Country: **IRAQ**

Exporting Country: **UNITED STATES of AMERICA**

1. Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form

1.1 Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): **vancomycin 1 GM**

1.2 Is this product licensed to be placed on the market for use in the exporting country? **Yes**

1.3 Is this product actually on the market in the exporting country? **Yes**

2.A.1 Product license number & date of issue: \_\_\_\_\_

2.A.2 Product license holder name & address: \_\_\_\_\_

2.A.3 Status of Product license holder: **Manufacturer**

2.A.3.1 Manufacturer name & address: \_\_\_\_\_

2.A.4 Is a summary basis for approval appended? **No**

2.A.5 Is the attached product information, complete and consonant with the license? **Yes**

2.A.6 Applicant name & address for certificate (if different from the license holder): \_\_\_\_\_

2.B.4 Remarks: **This FDA certification pertains to the product marketed in the United States of America.**

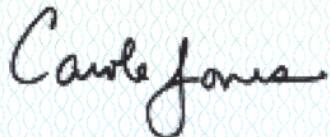
3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? **Yes**

3.1 Periodicity of routine inspections (years): \_\_\_\_\_ | **10**

3.2 Has the manufacture of this type of dosage form been inspected? **Yes**

3.3 Do the facilities and operations conform to GMPs as recommended by the WHO? (GMPs including 21 Code of Federal Regulations parts 210, 211, or ICH Q7A): **Yes, at time of inspection, site complies with FDA cGMP**

3.4 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**



Carole Jones, Division Director

Exports Compliance Branch

Division of Global Drug Distribution and Policy

Office of Drug Security, Integrity & Response

