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: **MEPN-KUEB** 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: **VANCOMYCIN, Injection, powder for solution**
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: **204107 12/28/2015**
2.A.2	Product license holder name & address: **Xellia Pharmaceuticals ApS, Dalslandsgade 11, Copenhagen DENMARK**
2.A.3	Status of Product license holder: **Manufacturer**
2.A.3.1	Manufacturer name & address: **Xellia Pharmaceuticals ApS, Dalslandsgade 11, Copenhagen S,2300 DENMARK**
2.A.4	Is a summary basis for approval appended? **No**
2.A.5	Is the attached product information, complete and consonent with the license? **Yes**
2.A.6	Applicant name & address for certificate (if different from the license holder): **Xellia Pharmaceuticals USA, LLC, 2150 E Lake Cook Rd Unit 1015, Buffalo Grove, IL 60089 United States of America**
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): **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 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

Carole Jones, Division Director
Exports Compliance Branch
Division of Global Drug Distribution and Policy
Office of Drug Security, Integrity & Response

This certificate conforms to the format recommended by the World Health Organization format revised October 1, 1997. Website: www.who.int