

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 - Approved Drug Product

Certificate Number A1BC-2D3E

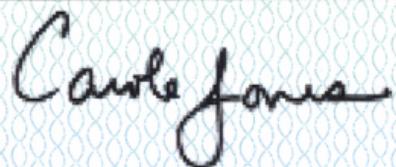
Certificate Issue Date: June 10, 2021

Certificate Expiration Date: June 09, 2023

Importing Country: KAZAKHSTAN

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):	
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:	
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, Division Director

Exports Compliance Branch

Division of Global Drug Distribution and Policy

Office of Drug Security, Integrity & Response

