State of Rhode Island and Providence Plantations

Department of State | Office of the Secretary of State

Nellie M. Gorbea, *Secretary of State*

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: United States of America

2. This Public document has been

   signed by — MICHELE M. JENKS

3. acting in the capacity of — Notary Public

4. bears the seal/stamp of — MICHELE M. JENKS

CERTIFIED

5. at Providence, Rhode Island

6. on Friday, January 04 2019

7. by Acting Deputy Secretary of State

8. No. 201901002650

9. Seal/Stamp

10. Signature

Maureen E. Ewing

Maureen Ewing
Acting Deputy Secretary of State

This Apostille only certifies the Authenticity of the signature and the capacity of the person who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears.

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TRUE COPY

I, Jodie Clark, do hereby affirm that the attached is a true copy of Rhodes Technologies' Certificate of Pharmaceutical Product – Active Pharmaceutical Ingredient (API). This information is to be used in the United Kingdom.

Jodie Clark
Title Sr. Regulatory Operations and eCTD Associate

Rhode Island

I, Michele Jenks, a Notary Public in the State of Rhode Island, do hereby certify that Jodie Clark personally appeared before me this day and acknowledged the due execution of the foregoing instrument.

Witness my hand and official seal, this the 2 day of January, 2019.

Michele Jenks, Notary Public
My commission expires: March 07, 2022

MICHELE M JENKS
Notary Public-State of Rhode Island
My Commission Expires
March 07, 2022

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 - Active Pharmaceutical Ingredient (API)

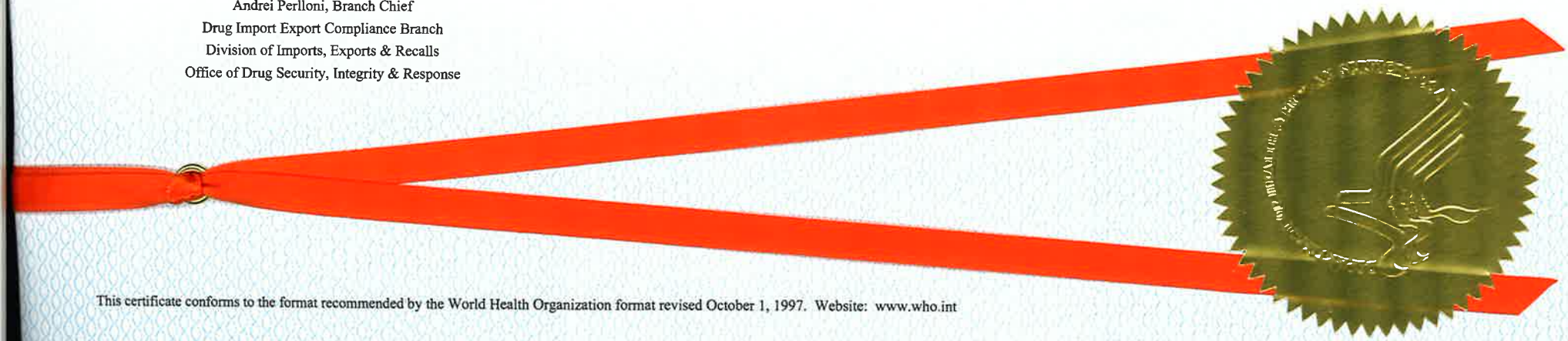
Certificate Number: **QZSV-P56E** Certificate Issue Date: **December 04, 2018** Certificate Expiration Date: **December 03, 2020**

Importing Country: **UNITED KINGDOM** Exporting Country: **UNITED STATES of AMERICA**

1.	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: **OXYCODONE HYDROCHLORIDE, Powder, non sterile**
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**
1.3	Is this product actually on the market in the exporting country? **Yes**
2.B.1	Applicant for certificate name & address: **Rhodes Technologies, 498 Washington St, Coventry, RI 02816 United States of America**
2.B.2	Status of Applicant: **Manufacturer**
2.B.2.1	Manufacturer name & address: **Rhodes Technologies, 498 Washington St, Coventry, RI 02816 United States of America**
2.B.3	Why is marketing authorization lacking? **Not Applicable**
2.B.4	Remarks:**The firm proposes to export the active pharmaceutical ingredients (API) 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.**
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**

Andrei Perlloni

Andrei Perlloni, Branch Chief
Drug Import Export Compliance Branch
Division of Imports, Exports & Recalls
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

RHODES
TECHNOLOGIES
498 WASHINGTON STREET COVENTRY, RI

QZSV-P56E

Item# 054000
OXYCODONE HCL USP PWD

CAS No. 124903 **NDC# 67509-006-50**

Drug Substance.

Caution: For manufacturing, processing or repacking.

U.S Federal Law prohibits dispensing without a prescription.

Storage: Keep container tightly closed in a dry and well-ventilated place. Material should be stored below 30 degrees C and 65% humidity.

LOT: XX-XXXXX

Released For Shipment

Retest Date:
Date Of Manufacture:

C-II