

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*

This public document

2. has been signed by *Andrei Perlloni*

3. acting in the capacity of *Branch Chief, Office of Drug Security, Integrity & Response*

4. bears the seal/stamp of *U.S. Department of Health and Human Services*

Certified

5. at Washington, D.C.

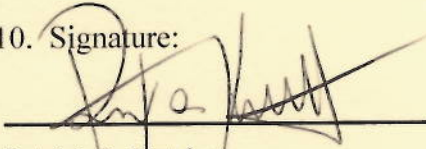
6. the *sixth* of March, 2019

7. by *Assistant Authentication Officer, United States Department of State*

8. No. *19023352-3*

9. Seal/Stamp:

10. Signature:


Patrick O. Hatchett

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 Issue Date: February 19, 2019

Certificate Expiration Date: February 18, 2021

Exporting Country: UNITED STATES of AMERICA

Certificate Number: B5KQ-NDVQ

Importing Country: CHILE

1.	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: DEXAMETHASONE USP MICRONIZED, 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: Pfizer, 7000 Portage Rd, Kalamazoo, MI 49001 United States of America
2.B.2	Status of Applicant: Manufacturer
2.B.2.1	Manufacturer name & address: Pfizer, 7000 Portage Rd, Kalamazoo, MI 49001 United States of America
2.B.3	Why is marketing authorization lacking? Not Required
2.B.4	Remarks: Pharmacia & Upjohn Company LLC, 7000 Portage Road, Kalamazoo, Michigan 49001, is a wholly owned subsidiary of Pfizer, Inc.; The firm proposes to export the active pharmaceutical ingredients (API) listed above, which when properly labeled with statement "Caution: For further manufacturing, processing or repackaging", 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(b)(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 2) 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



16/434

Material: H001221900

KEEP CONTAINER TIGHTLY CLOSED

DEXAMETHASONE USP MICRONIZED

DOM:

Label Copy: 79559

CAUTION: FOR MANUFACTURING, PROCESSING, OR REPACKING
RX ONLY

REFER TO MATERIAL SAFETY DATA SHEET FOR HAZARD WARNINGS AND SAFETY INFORMATION

Quantity: 999.99 KG

**PHARMACIA & UPJOHN COMPANY LLC - KALAMAZOO,
MICHIGAN 49001, USA**

Pharmacia and Upjohn Company LLC Division of Pfizer Inc 7000 Portage Road Kalamazoo, MI 49001	Emergency Telephone: +1-269-833-5122
Material Name: Dexamethasone Trade Name: Not determined Synonym: Dexamethasone USP, Dexamethasone USP Micronized	EC Number: 200-003-9 Registration Number: CAS No: 50-02-2
Danger H360 - May damage fertility or the unborn child May form combustible dust concentrations in air P201 - Obtain special instructions before use P202 - Do not handle until all safety precautions have been read and understood P210 - Keep away from heat/sparks/open flame/hot surfaces - No smoking P240 - Ground/Bond container and receiving equipment P280 - Wear protective gloves/protective clothing/eye protection/face protection P308 + P313 - IF exposed or concerned: Get medical attention/advise P405 - Store locked up P501 - Dispose of contents/container in accordance with all local and national regulations High thermal potential	