MUNDIPHARMA LABORATORIES GmbH

Basel (Switzerland)

A QUIEN INTERESE:

La presente, es para dejar constancia que los registros listados de OXYCONTIN (Oxicodona clorhidrato) Comprimidos Recubiertos de Liberación Prolongada, los cuales son exportados a Chile a ALPES CHEMIE S.A. son fabricados y exportados por PURDUE PHARMACEUTICALS LP, Son productos fabricados bajo normas GMP y aprobados por la FDA. Se adjunta declaración donde se certifica que el GMP actual para el fabricante tiene vigencia hasta el 12.12.2019.

Nombre Prducto	Reg. ISP
OXYCONTIN Comprimidos Recubiertos de Liberación Prolongada 10 mg	Reg. ISP Nro. F-510
OXYCONTIN Comprimidos Recubiertos de Liberación Prolongada 20 mg	Reg. ISP Nro. F-511
OXYCONTIN Comprimidos Recubiertos de Liberacón Prolongada 40 mg	Reg. ISP Nro. F-512

Se extiende el presente certificado a petición del titular de los registros en Chile.

Cordialmente,

_____

Alba Rocio Castillo Pabón – Q.F. & MSc.
Gerente Regional Asuntos Regulatorios & D.T.
Colombia, Países Andinos y Cono Sur

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: **M4WX-ZAFK** Certificate Issue Date: **December 13, 2017** Certificate Expiration Date: **December 12, 2019**

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

1.	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: **OXYCONTIN CONTROLLED-RELEASE TABLET, Tablet, extended release**
1.1	Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): **oxycodone hydrochloride 10 MG**
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: **022272 04/05/2010**
2.A.2	Product license holder name & address: **Purdue Pharma L.P., 201 Tresser Blvd, Stamford, CT 06901 United States of America**
2.A.3	Status of Product license holder: **Manufacturer**
2.A.3.1	Manufacturer name & address: **Purdue Pharmaceuticals L.P., 4701 Purdue Drive, Wilson, NC 27893 United States of America**
2.A.4	Is a summary basis for approval appended? **Yes**
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): **N/A**
2.B.4	Remarks: **Packaging Facility: Anderson Packaging Inc, 4545 Assembly Drive, Morristown, IL 61109**
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

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

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, Drug Import Export Compliance Branch

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

Certified

5. at Washington, D.C.

6. the twenty-sixth of January, 2018

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

8. No. 18017097-5

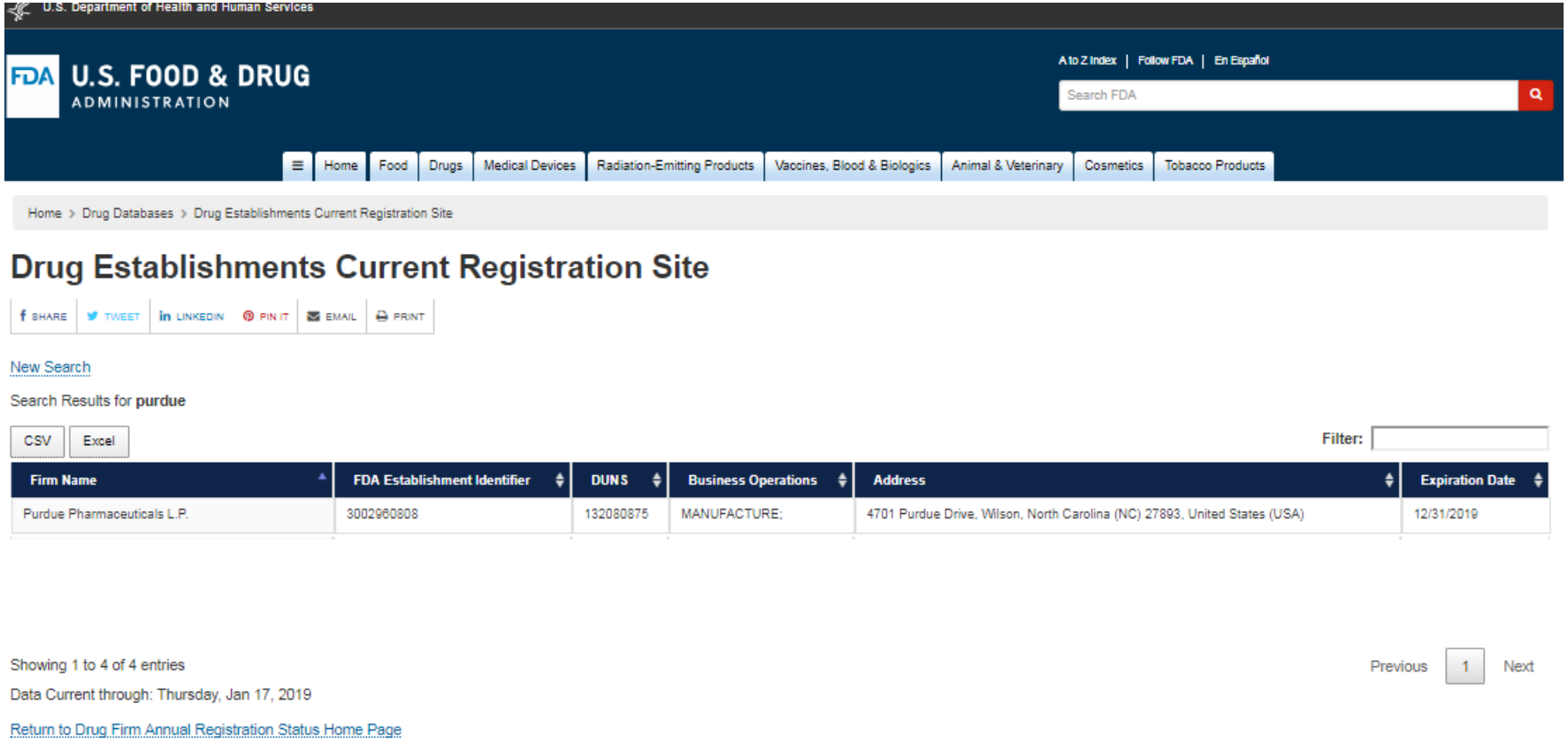
9. Seal/Stamp:

10. Signature:

Zelda Daley

PLANTA FABRICACION OXYCONTIN 10 – 20 Y 40 MG - FDA vigente 31.12.2019

https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm



U.S. Department of Health and Human Services

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Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Purdue Pharmaceuticals L.P.	3002960808	132080875	MANUFACTURE;	4701 Purdue Drive, Wilson, North Carolina (NC) 27893, United States (USA)	12/31/2019

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