16036605-13

United States of America

DEPARTMENT OF STATE

To all to whom these presents shall come, Greetings:

I Certify That the document hereunto annexed is under the Seal of the Department of Health and Human Services, United States of America, and that such Seal is entitled to full faith and credit.*

For the contents of the annexed document,the Department assumes no responsibility
This certificate is not valid if it is removed or altered in any way whatsoever

In testimony whereof, I, John F. Kerry, Secretary of State , have hereunto caused the seal of the Department of State to be affixed and my name subscribed by the Assistant Authentication Officer, of the said Department, at the city of Washington, in the District of Columbia, this twenty-sixth day of May, 2016.

John F. Kerry
Secretary of State

By Matthews
Assistant Authentication Officer,
Department of State

Issued pursuant to CHXIV, State of Sept. 15, 1789, 1 Stat. 68-69; 22 USC 2657; 22USC 2651a; 5 USC 301; 28 USC 1733 et. seq.; 8 USC 1443(f); RULE 44 Federal Rules of Civil Procedure.

Consulado de Chile
Washington, D.C.

Ministerio de Relaciones Exteriores
Embajada de Chile en Estados Unidos
Sección Consular

El Cónsul que suscribe, certifica la autenticidad de la firma de:

VEDA L. MATTHEWS

ASSISTANT AUTHENTICATION OFFICER,
DEPARTMENT OF STATE

CONSULADO DE CHILE
WASHINGTON, D.C.

ARTURO GIADALA SUKNI
Cónsul de Chile

4 LEGALIZADA EN EL MINISTERIO
DE RELACIONES EXTERIORES DE CHILE
FIRMA DEL Sr.(a)

8 JUN 2016

Miguel F. EYES VARGAS
Oficial de Legalizaciones

SERVICIO CONSULAR
2016
CHILE-US$
10

Actuación N° 2411 Arancel Art. N° 4/10
Derechos US$ 12 Diferencia 10% —
Total percibido en US$: 12.—
Pagado en moneda del país: US$
Washington, DC 01 JUN 2016.—

United States Food and Drug Administration

Center for Drug Evaluation and Research (CDER)
10903 New Hampshire Avenue, Silver Spring, MD 20993, USA
Email: CDERExportCertificateProgram@fda.hhs.gov Telephone: (301) 796-4950

Certificate of a Pharmaceutical Product

Certificate Issue Date: **5/16/2016**
Certificate No. **05-0013-2016-11-CL**

Certificate Expiration Date: **5/16/2018**
Exporting Country: **United States of America**
Importing Country: **Chile**

1. International or National Nonproprietary Name (if applicable) and dosage form:
1.1 Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): **DEPAKOTE® ER (divalproex sodium) Extended-Release Tablets, 500mg**
See Attachments

1.2 Is this product **licensed** to be placed on the market for use in the exporting country? **YES - See Block A**

1.3 Is this product actually on the market in the exporting country? **Yes**

A	B
2A.1 Number of product-license and date of issue: **21-168 8/4/2000**	2B.1 Applicant for certificate (name and address)
2A.2 Product-license holder: **AbbVie Inc.**	2B.2 Status of Applicant:
2A.3 Status of product-license holder: **Manufacturer**	2B.3 Why is authorization lacking? **not required** **not applicable** **under consideration** **refused**
2A.4 Is an approved summary basis appended? **No**	2A.3.1 or 2B.2.1 Manufacturer name and address: **ABBVIE LTD, Barceloneta, PR 00617**
2A.5 Is the attached product information complete and consonant with the license? **Yes**	2B.4 Remarks: **Manufacturing Facility: AbbVie LTD, KM 58.0 Carretera 2 Cruce Davila, Barceloneta, Puerto Rico (PR) 00617, United States (USA)**
2A.6 Applicant for certificate if different from the license holder (name and address):	

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 inspection (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 GMP as recommended by the WHO? (GMP including 21 CFR Parts 210, 211 or ICH Q7A) **Yes, at time of inspection, site complies with U.S. CGMP**
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**

This certificate conforms to the format recommended by the World Health Organization format revised 10/1

Karen C. Corallo

Karen C. Corallo , Director
Imports Exports Compliance Branch
Division of Imports, Exports and Recalls
Office of Drug Security, Integrity & Response
Center for Drug Evaluation and R

3.2.P.1 Description and Composition of the Drug Product Depakote ER, Tablets, 500 mg

Depakote ER Tablets, 500 mg, containing Divalproex Sodium as the active substance has been developed by Abbott Laboratories. The dosage form is extended release tablet at 500 mg. The qualitative and quantitative composition is presented in P.1 Table

P.1 Table 1. Target Composition of Depakote ER, Tablets, 500 mg

Component	Quality Standard	Function	Amount/Unit
Water, Purified, USP(1)	USP	Binder	Approx 120.0 mg
Hypromellose 2208, USP, 15,000 CPS (Premium CR)	USP	Control release polymer	300.000 mg
Cellulose, Microcrystalline, NF/EP (Avicel pH-101)	NF, Ph. Eur.	Granulation aid	50.000 mg
Lactose, Monohydrate, NF, Powder, Regular	NF	Granulation aid	81.900 mg
Divalproex Sodium (Sodium Hydrogen Divalproate)(2) Divalproex Sodium (SHD); MFD. From AI Valproic Acid (51165) Label Claim: 500 mg Valproic Acid Equivalent/Tablet	N/A	Active Ingredient	538.100 mg
Silicon Dioxide, NF (Syloid 244 FP)	NF	Lubricant	30.000 mg
Color coating Liquid, Opadry II Gray - 200 mg(3)			
Potassium Sorbate, NF, Powder	NF	Preservative	0.200 mg
Opadry II, Y-22-17515, Gray	N/A	Color coat	40.000 mg
Water, Purified, USP(4)	USP	Solvent	159.800 mg
Gloss Coating Liquid, Opadry Clear - 100 mg(3)			
Potassium Sorbate, NF, Powder	NF	Preservative	0.200 mg
Opadry, YS-1-19025-A, Clear	N/A	Clear coat	10.000 mg
Water, Purified, USP(4)	USP	Solvent	89.800 mg
Other			
Ink, Blue (Colorcon Opacode S-1-4160)	N/A	Ink	Approx 0.809 µL
Alcohol, Isobutyl(5)	N/A	Solvent	Approx 0.809 µL

Regulatory Notes:

(1) Removed during drying process

(2) Contains a 1.5% excess for loss in milling

(3) Amount includes an approximate 30% manufacturing excess

(4) Removed during coating process

(5) Removed during printing process

Exp.

Lot

NDC 0074-7126-13
100 Tablets

DEPAKOTE® ER

DIVALPROEX SODIUM
EXTENDED-RELEASE
TABLETS

500 mg Valproic Acid Activity

Dispense the accompanying Medication Guide to each patient.

Rx only

abbvie

Do not accept if seal over bottle opening is broken or missing.
Dispense in a USP tight, light-resistant container.
Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature]
Each tablet contains:
Divalproex sodium equivalent to valproic acid .....500 mg
See Package Insert for prescribing information.
Manufactured by
AbbVie LTD.
Barceloneta, PR 00617
For
AbbVie Inc.
North Chicago, IL 60064, USA

04-A916-R3

(Nos. 3826 and 7126) 03-B118-R22 Rev. March, 2015

Depakote® ER

Divalproex Sodium
Extended-Release Tablets

Rx only

Tear at perforation to dispense Medication Guide

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of

State

ficer,