Health Canada / Santé Canada

CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

This certificate conforms to the format recommended by the World Health Organization
(Superscript numbers refer to explanatory notes located at the end of the certificate)

Exporting (certifying) country: **CANADA** No. of Certificate: **74989**

Importing (requesting) country: **CHILE**

1. Name and dosage form of the product:
INSPRA **TABLET**

1.1 Active ingredient(s)[2] and amount(s) per unit dose:[3]
EPLERENONE 25 MG

For complete composition including excipients, see attached: [4] **No**

1.2 Is this product licensed to be placed on the market for use in the exporting country? [5] **Yes**

If YES, continue with section 2A and leave section 2B blank.
If NO, leave question 1.3 and section 2A blank and continue with section 2B.

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

DIN: 02323052
MARKETED: 2020-05-13

2A.1 Number of product license and date of issue:[7]

2A.2 Product license holder (name and address):

UPJOHN CANADA ULC
17300 TRANS CANADA HIGHWAY
KIRKLAND,QUEBEC
CANADA,H9J 2M5

2A.3 Status of license holder:[8] **C**

2A.3.1 For categories[9] (B) and (C) the name and address of the manufacturer producing the dosage form is:

PFIZER PHARMACEUTICALS, LLC
ROAD 689 KM 1.9
VEGA BAJA, PR
00693, UNITED STATES

2A.4 Is a summary basis for approval appended ?[10] **Not Applicable**

2A.5 Is the attached product information complete and consonant with the license?[11] **Not Required**

2A.6 Applicant for certificate, if different from license holder (name and address):[12]

PFIZER CANADA ULC
17300 TRANS-CANADA HIGHWAY
KIRKLAND,QUEBEC
CANADA,H9J 2M5

THE DEPARTMENT OF FOREIGN AFFAIRS, TRADE AND DEVELOPMENT CANADA HAS DULY AUTHENTICATED THE SIGNATURE AFFIXED ON THE UNDERLYING DOCUMENT, OF:

LE MINISTÈRE DES AFFAIRES ÉTRANGÈRES, COMMERCE ET DÉVELOPPEMENT CANADA A DÛMENT AUTHENTIFIÉ LA SIGNATURE APPOSÉE SUR LE DOCUMENT SOUS-JACENT, DE:

FOR THE DEPUTY MINISTER OF FOREIGN AFFAIRS/POUR LE SOUS-MINISTRE DES AFFAIRES ÉTRANGÈRES:

Tina Wishak

DEC 1 n 2020

THE DEPARTMENT DOES NOT VALIDATE THE CONTENT OF THE UNDERLYING DOCUMENT / LE MINISTÈRE NE VALIDE PAS LE CONTENU DU DOCUMENT SOUS-JACENT

OTTAWA, CANADA

I, Waqas Chughtai, Regulatory Affairs Associate, attest to the veracity of the information herewith on behalf of Upjohn Canada ULC.

Signature: Chughtai Date: NOV 25 2020

Declared under oath before me via videoconference in St-Clet, Quebec on November 25, 2020
Date

JULIE MARSHALL, Commissioner for Oaths for Quebec; Commissioner No. 230228
Name print

Julie Marshall
Name Signature

Canada

CONSULADO DE CHILE EN
OTTAWA, CANADA

El Cónsul de Chile que suscribe certifica la autenticidad de la firma de doña TINA WISHAK, Oficial de Legalizaciones des Ministerio de Relaciones Exteriores de Canadá.

Ottawa, 16 de Diciembre de 2020

CONSULADO DE CHILE OTTAWA

JULIO FIGUEROA
Primer Secretario
Cónsul

SERVICIO CONSULAR 2020 10 US$ CHILE CLP

SERVICIO CONSULAR 2020 2 2

CONSULADO DE CHILE OTTAWA

Actuación N° 520 Derechos percibidos US$ 12
Arancel Art. N° 4-10 / ( )
Ottawa, 16 de Diciembre 2020

Health Canada / Santé Canada

2B.1 Applicant for certificate (name and address):

2B.2 Status of applicant:[8]

2B.2.1 For categories (B) and (C) the name and address of the manufacturer producing the dosage form is:[9]

2B.3 Why is marketing authorization lacking?

2B.4 Remarks:[13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? [14] **Not Applicable**

If NO or NOT APPLICABLE, proceed to question 4

3.1 Periodicity of routine inspections (years):

3.2 Has the manufacture of this type of dosage form been inspected?

3.3 Do the facilities & operations conform to GMP as recommended by the WHO? [15]

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? [16] **Yes**

If NO, explain:

Address of certifying authority

Regulatory Operations and Enforcement Branch
Health Product Compliance Directorate
200 Eglantine Driveway, Tunney's Pasture
Ottawa, Ontario K1A 0K9

Digitally signed by Balachandran, Janan
DN: C=CA, O=gc, OU=HC-SC, CN="Balachandran, Janan"
Date: 2020-11-15 11:56:20

Signature: _____ Date: **2020-11-13**

Name of authorized person **JANAN BALACHANDRAN**

This certificate expires 1 year from the date of issue

Canada