



Ontario

MINISTRY OF GOVERNMENT AND CONSUMER SERVICES

THIS IS TO CERTIFY THAT

PAMELA LYNN TE GROTENHUIS

in the Province of Ontario whose name is subscribed to the attached Instrument, was, at the time of subscribing thereto, a **NOTARY PUBLIC** appointed for a period of three years from the 30th day of May, 2016. It is effective only in the County of Brant, and only while you are working for Apotex Pharmachem Inc., and is limited to the attestation of instruments and the taking of affidavits for work in connection with the business of that company.

I FURTHER CERTIFY THAT I have compared the signature of the said **NOTARY PUBLIC** subscribed to the attached Instrument with the specimen signature of the said **NOTARY PUBLIC** filed in this office and verily believe the said signature to be genuine; and THAT I have compared the impression of the Seal of the said **NOTARY PUBLIC** appearing on the attached Instrument with the specimen of the Seal filed in this office and verily believe the impression of the Seal to be genuine.

IN TESTIMONY WHEREOF I have hereunto set my Hand and affixed the Seal of the Ministry of Government and Consumer Services of the Province of Ontario at the City of Toronto in the said Province this eleventh day of April, A.D. 2018.

for the MINISTER OF GOVERNMENT AND CONSUMER SERVICES





40322

SIN TEXTO

SECRETARÍA DE RELACIONES EXTERIORES

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NO. DE ORDEN:	TOR/406/18
DERECHOS EN MONEDA LOCAL:	48.00
DERECHOS EN DÓLARES:	36.00

F-153 CONSULADO GENERAL DE MEXICO
TORONTO, ONT., CANADA

SERVICIO EXTERIOR MEXICANO

EL(LA) SUSCRITO(A) DIEGO ESPINOSA LEON, CONSUL DE MEXICO EN TORONTO, ONTARIO, CANADÁ, CERTIFICA QUE EL(LA) FIRMA Y SELLO DE MINISTRY OF GOVERNMENT AND CONSUMER SERVICES PUESTO(A) EN EL (LA) DOCUMENTO ADJUNTO(A), EXPEDIDO(A) POR EL(LA) NOTARIO PUBLICO PAMELA LYNN TE GROTEHUIS, A FAVOR DE APOTEX PHARMACHEM INC., COINCIDE CON EL QUE SE TIENE REGISTRADO(A) EN ESTA OFICINA.—

LUGAR	FECHA
TORONTO, ONTARIO, CANADÁ	18 ABRIL 2018

NOTA: ESTA LEGALIZACIÓN NO PREJUZGA DE LA VALIDEZ DEL CONTENIDO DEL DOCUMENTO ANEXO

FIRMA DIGITAL:

Cargo:CONSUL | Firmante: DIEGO ESPINOSA LEON | Fecha:2018-4-18 13:56:3 | No. Serie:00001000000406363222 | Datos estampillados 902B1AD5F8DE05EC64B20AFD28ACB4CC868FBCAD
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SIN TEXTO

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Confirmation no. (given by the issuing regulatory authority): 1107D2F3

1. Name and address of site (including building number, where applicable): Apotex Pharmachem Inc., 34 Spalding Drive, Brantford, Ontario, N3T 6B8, Canada

2. Manufacturer's licence number(s):¹ 101257

REGARDING THE MANUFACTURING PLANT UNDER (1) OF THE FOLLOWING ACTIVE SUBSTANCE(S) EXPORTED TO THE EU FOR MEDICINAL PRODUCTS FOR HUMAN USE

Active substance(s): ²	Activity(ies): ³
Adefovir Dipivoxil	Chemical synthesis
Alendronate Sodium Trihydrate	Chemical synthesis
Alfuzosin Hydrochloride	Chemical synthesis
Anastrozole	Chemical synthesis
Aripiprazole	Chemical synthesis
Atomoxetine Hydrochloride	Chemical synthesis
Atorvastatin Propylene Glycol Solvate	Chemical synthesis
Benzotropine Mesylate	Chemical synthesis
Budesonide	Chemical synthesis
Candesartan Cilexetil	Chemical synthesis
Cevimeline Hydrochloride	Chemical synthesis
Darifenacin Hydrobromide	Chemical synthesis
Dasatinib	Chemical synthesis
Deferiprone	Chemical synthesis
Desvenlafaxine	Chemical synthesis
Desvenlafaxine Succinate Monohydrate	Chemical synthesis
Dexlansoprazole Anhydrate	Chemical synthesis
Erlotinib Hydrochloride	Chemical synthesis
Esomeprazole Magnesium	Chemical synthesis
Ibandronate Sodium	Chemical synthesis
Imatinib Mesylate	Chemical synthesis
Loteprednol Etabonate	Chemical synthesis
Lubiprostone	Chemical synthesis
Memantine Hydrochloride	Chemical synthesis
Methacholine Chloride	Chemical synthesis
Midodrine Hydrochloride	Chemical synthesis
Moexipril Hydrochloride	Chemical synthesis
Montelukast Sodium	Chemical synthesis
Nabilone	Chemical synthesis
Olanzapine	Chemical synthesis
Palbociclib	Chemical synthesis

Certified True Copy

Pamela Lynn te Grotenhuis

Pamela Lynn te Grotenhuis,
Notary Public, County of Brant,
limited to the attestation of instruments
and the taking of affidavits,
for Apotex Pharmachem Inc.
Expires May 30, 2019

¹ Where the regulatory authority issues a licence for the site. Record 'not applicable' in case where there is no legal framework for issuing of a licence.

² Identification of the specific active substances through an internationally-agreed terminology (preferably international nonproprietary name).

³ For example, 'Chemical synthesis', 'Extraction from natural sources', 'Biological processes', 'Finishing steps'.



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Active substance(s): ²	Activity(ies): ³
Paliperidone	Chemical synthesis
Pantoprazole Magnesium Dihydrate	Chemical synthesis
Pantoprazole Sodium Sesquihydrate	Chemical synthesis
Paroxetine Hydrochloride (anhydrous)	Chemical synthesis
Posaconazole	Chemical synthesis
Risedronate Sodium Hemipentahydrate	Chemical synthesis
Rivaroxaban	Chemical synthesis
Rivastigmine	Chemical synthesis
Rivastigmine Tartrate	Chemical synthesis
Rufinamide	Chemical synthesis
Sitagliptan Phosphate	Chemical synthesis
Tasimelteon	Chemical synthesis
Tofacitinib Citrate	Chemical synthesis
Vilazodone	Chemical synthesis
Warfarin Potassium Clathrate	Chemical synthesis
Warfarin Sodium Clathrate	Chemical synthesis
Ziprasidone Hydrochloride (amorphous)	Chemical synthesis
Ziprasidone Hydrochloride (crystalline)	Chemical synthesis

THE ISSUING REGULATORY AUTHORITY HEREBY CONFIRMS THAT:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.⁴

Date of inspection of the plant under (1): Name of inspecting authority if different from the issuing regulatory authority:

- Health Canada inspected the facility on December 11-20, 2017.

This written confirmation remains valid until December 11, 2020.

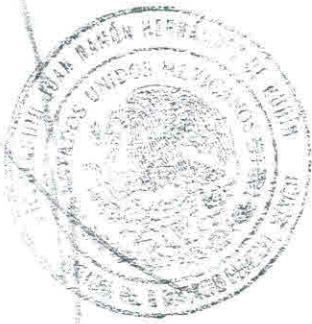
The authenticity of this written confirmation may be verified with the issuing regulatory authority.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Graham Spry Building, 2nd Floor, 250 Lanark Avenue, Address Locator #2002A, Ottawa, Ontario, Canada, K1A 0K9

⁴ qdefect@ema.europa.eu.



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Name and function of responsible person:

Kimby Barton, Director, Licensing and Inspection Bureau, Health Products and Food Branch
Inspectorate, Health Canada

E-mail, Telephone no., and Fax no.:

kimby.barton@hc-sc.gc.ca

Tel. no.: 613-954-2996

Signature

Date

Kimby N. Barton

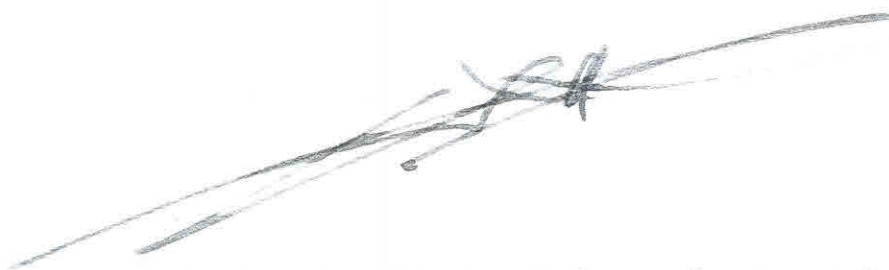
2018-03-07

CLAUDIO JUAN RAMÓN HERNÁNDEZ DE RUBÍN, titular de la
notaría número seis de la Ciudad de México, CERTIFICO: Que
esta copia fotostática en cinco páginas de las cuales las
cuatro primeras, van selladas y rubricadas por mí, es una
reproducción fiel y exacta de su **original**, con el que la
comparé y a la que corresponde el número de registro
CUARENTA MIL TRESCIENTOS VEINTIDÓS de esta fecha, ante
mí. -----

Doy fe. -----

Ciudad de México, a veintiséis de abril de dos mil dieciocho.--

EED.



LICENCIADO CLAUDIO JUAN RAMÓN HERNÁNDEZ DE RUBÍN
TITULAR DE LA NOTARÍA NÚMERO SEIS
DE LA CIUDAD DE MÉXICO

