Ontario

MINISTRY OF GOVERNMENT AND CONSUMER SERVICES

I HEREBY CERTIFY AS FOLLOWS:

ELENA PRIARO

of the City of Toronto, 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 25th day of October, 2014. It is effective only in the City of Toronto, and only while you are working for Apotex Inc., and is limited to the attestation of instruments and the taking of affidavits in connection with the business of that company and its associated companies.

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 sixth day of January, A.D. 2015.

Christina Netto

for the MINISTER OF GOVERNMENT AND CONSUMER SERVICES

CONSULADO GENERAL DE CHILE
EN TORONTO, CANADA

El Cónsul General de Chile que suscribe certifica la autenticidad de la firma de doña Christina Netto Secretario del Gobierno Provincial de Ontario Canada.

Actuación Nº 127 Arancel Art. Nº 4-10 Derechos percibidos US$ 12.

Toronto, 13 de Ene de 2015

ALFREDO HURTADO MAURIC
Canciller del Consulado General de Chile
Toronto, Canada

Art. 345 CPC. Se legaliza firma, no contenido
Legalizada en el Ministerio de Relaciones Exteriores de Chile
Firma del Señor,

27 ENE 2015

LAURA DE LA VEGA FERNÁNDEZ
Oficial de Legalizaciones

CANADA)
)
Province of Ontario)
)
To Wit)
)

TO ALL WHOM THESE PRESENTS

may come, be seen or known

I, **Elena Priaro**, a Notary Public, in and for the Province of Ontario, by Royal Authority duly appointed, residing in the City of Mississauga, in said Province, do certify and attest that the paper-writing annexed hereto are documents produced and shown to me and purporting to be a true original of the **CERTIFICATE OF A PHARMACEUTICAL PRODUCT NO. 58413 Apo Rosuvastatin 10 mg Tablet** issued by Health Canada (duly signed by Neil Barkat) with Qualitative and Quantitative formula, on the 12th day of September, 2014, exportation for Chile.

An act whereof being requested I have granted under my Notarial Form and Seal of Office to serve and avail as occasion shall or may require.

IN TESTIMONY WHEREOF I have hereto subscribed my name and affixed my Notarial Seal of Office at Toronto, this 27th day of October, 2014.

A Notary Public in and for the Province of Ontario

ELENA PRIARO, Notary Public,
City of Toronto, limited to the
attestations of instruments and the
taking of affidavits for Apotex Inc.,
and its associated **companies.**
Expires October **25, 2017.**

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: 58413

Importing (requesting) country: **CHILE**

1. Name and dosage form of the product:
APO-ROSUVASTATIN **TABLET**

1.1 Active ingredient(s)[2] and amount(s) per unit dose:[3]
ROSUVASTATIN (ROSUVASTATIN CALCIUM) 10 MG

For complete composition including excipients, see attached:[4] **Yes**

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[6]

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

2A.1 Number of product license and date of issue:[7] **02337983** **2012-04-02**

2A.2 Product license holder (name and address):
APOTEX INCORPORATED
150 SIGNET DRIVE
TORONTO,ONTARIO
CANADA,M9L 1T9

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

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

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] **Yes**

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

Canada

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] **Yes**

If NO or NOT APPLICABLE, proceed to question 4

3.1 Periodicity of routine inspections (years): **2**

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

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

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?[16] **Not Applicable**

If NO, explain:

Address of certifying authority

Inspectorate Ottawa
Health Products & Food Branch Inspectorate
250 Lanark Ave
AL: 2002A
Ottawa, ON, K1A 0K9
Tel: (613) 957-1166

Signature: _____ Date: **2014-09-12**

Name of authorized person **NEIL BARKAT**

This certificate expires 1 year from the date of issue

Canada

Health Products and Food Branch Inspectorate
Inspectorat de la Direction générale des produits de santé et des aliments
2014
Health Canada Santé Canada
Canada

Explanatory Notes

/www.who,intfmedicineslorganizationlqsm/activitiesfdrugregullcertification/modcert.html (dated: 2004-07-28)

This certificate, which is in the format recommended by the WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

02 Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.

03 The formula (complete composition) of the dosage form should be given on the certificate or be appended.

04 Details of quantitative composition are preferred but their provision is subject to the agreement of the product-licence holder.

05 When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.

06 Sections 2A and 28 are mutually exclusive.

07 Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.

08 Specify whether the person responsible for placing the product on the market:
a) manufactures the dosage form;
b) packages and/or labels a dosage form manufactured by an independent company; or
c) is involved in none of the above.

09 This information can only be provided with the consent of the product-licence holder or, in the case of non-registered products, the applicant Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product licence. If the production site is changed, the licence has to be updated or it is no longer valid.

10 The Health Products and Food Branch Inspectorate (HPFB Inspectorate) does not issue a document to the license holder that summarizes the technical basis on which the product has been licensed. This information is contained in the detailed marketing application submitted by the license holder and maintained by HPFB Inspectorate. In those instances where the license holder has provided certified technical information for the product, it is appended to the certificate.

11 Product information (Ex. product monographs, labeling, patient information sheet) is approved at the time of product registration and periodically thereafter when the need arises, Product information submitted by the applicant is not systematically reviewed prior to the issuance of the certificate. The applicant is required to provide written certification regarding the accuracy, completeness and concordance of the information with the currently approved version

12 When the applicant is different from the licence holder, permission for issuing the certificate is required from the product licence holder. The applicant must provide evidence of the licence-holder's permission to Health Canada.

13 Please indicate the reason that the applicant has provided for not requesting registration.
a) the product has been developed exclusively for the treatment of conditions — particularly tropical diseases — not endemic in the country of export;
b) the product has been reformulated with a view to improving its stability under tropical conditions;
c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
e) any other reason, please specify.

14 Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

15 The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No. 823, 1992, Annex 1. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).

16 This section is to be completed when the product-licence holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

APOTEX
ADVANCING GENERICS

TRADE NAME: APO-ROSUVASTATIN

PROPER NAME: Rosuvastatin Calcium Tablets 10 mg and 20 mg

DESCRIPTION:

Dosage Form	Strength	Description
Tablets	10 mg	Pink, round, biconvex, film-coated tablet.Engraved "APO" on one side, "ROS" over "10" on the other side.
	20 mg	Pink, round, biconvex, film-coated tablet. Engraved "APO" on one side, "ROS" over "20" on the other side.

THE MANUFACTURER HAS CERTIFIED THAT THE INFORMATION AND MATERIAL INCLUDED ARE ACCURATE AND ARE COPIES OF INFORMATION AND MATERIAL CURRENTLY ON FILE WITH HPFB

SEP 12 2014

HEALTH PRODUCT AND FOOD BRANCH INSPECTORATE
HPFBI - HEALTH CANADA

Apotex Inc. 150 Signet Drive, Toronto, ON M9L 1T9
Tel: (416) 749-9300 Fax: (416) 401-3849
www.apotex.com

APOTEX
ADVANCING GENERICS

QUALITATIVE AND QUANTITATIVE FORMULA

Component and Quality Standard (and Grade, if applicable)	Function of component	Quantity mg/tablet		
		% w/w	10 mg	20 mg
Core				
Rosuvastatin Calcium*IH	Active	7.067	10.6	21.2
Lactose Monohydrate NF (Spray Dried)*	Diluent			
Microcrystalline Cellulose NF (PH102)	Diluent/ Binder			
Crospovidone NF	Disintegrant			
Magnesium Stearate NF	Lubricant			
Colloidal Silicon Dioxide NF	Glidant			
	Total Core Weight			
Film Coating				
Hydroxypropyl Methylcellulose 2910 USP E5	Film Forming Polymer			
Hydroxypropyl Cellulose NF, Type LF	Film Forming Polymer			
Polyethylene Glycol 8000 NF	Plasticizer			
Titanium Dioxide USP	Opacifer			
Red Ferric Oxide NF – Orange Shade #34690	Colourant			
Purified Water USP**	Solvent			
Total (excluding water)				
Coated Tablet Weight				

*Amount based on theoretical 100% potency of rosuvastatin calcium drug substance on the dried basis and typical water content (~1.8%). Actual quantity of rosuvastatin calcium is to be adjusted based on as is assay for Rosuvastatin Lactose Monohydrate to be used for weight adjustment.
** Purified water evaporates during coating

Apotex Inc. 150 Signet Drive, Toronto, ON M9L 1T9
Tel: (416) 749-9300 Fax: (416) 401-3849
www.apotex.com


CONSULADO GENERAL DE CHILE
OTTAWA CANADA