Health Canada Santé Canada

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

GOOD MANUFACTURING PRACTICE CERTIFICATE

This certificate conforms to the format recommended by the World Health Organization.
(Superscript numbers refer to WHO Explanatory Notes)

Exporting (certifying) country: **CANADA**

No. of Certificate: **57196**

Importing (requesting country): **COLOMBIA**

1. Name and dosage form of the product:
OINTMENTS, CREAMS, LIQUIDS, SUSPENSIONS, SOLID DOSE TABLETS, CAPSULES

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

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] **N/A**
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 on the market in the exporting country? **N/A**
THIS CERTIFICATE DOES NOT RELATE TO ANY SPECIFIC PRODUCT.

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

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

2A.3 Status of licence holder[8]:

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

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

2A.5 Is the attached product information complete and consonant with the licence?[11]
not required

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

2B.1 Applicant for certificate (name and address):
GLAXOSMITHKLINE INC.
7333 MISSISSAUGA ROAD
MISSISSAUGA, ONTARIO
CANADA L5N 6L4

2B.2 Status of applicant[8]: **C**

2B.2.1. For categories (B) and (C) the name and address of the manufacturer producing the dosage form is [9]:
PRODUCTION OF PRODUCT:
VALEANT PHARMACEUTICAL INTERNATIONAL, INC.
100 LIFE SCIENCE PARKWAY
STEINBACH, MANITOBA
R5G 1Z7

2B.3 Why is marketing authorization lacking?

Canada



2B.4 Remarks[13] **GMP CERTIFICATE**

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] **YES**
If no, explain:.

Address of certifying authority:

Inspectorate Ottawa
Health Products and Food Branch Inspectorate
250 Lanark Avenue
AL 2002A
Ottawa, Ontario Canada K1A 0K9
Tel: (613) 957-1166

THE DEPARTMENT OF FOREIGN AFFAIRS, TRADE AND DEVELOPMENT CANADA HAS DULY AUTHENTICATED THE FOREGOING SIGNATURE OF:

LE MINISTÈRE DES AFFAIRES ÉTRANGÈRES, COMMERCE ET DÉVELOPPEMENT CANADA A DÛMENT AUTHENTIFIÉ LA SIGNATURE QUI PRÉCÈDE:

AUTHENTICATED FOR THE DEPUTY MINISTER OF FOREIGN AFFAIRS BY:

AUTHENTIFIÉ POUR LE SOUS-MINISTRE DES AFFAIRES ÉTRANGÈRES PAR:

Department of Foreign Affairs, Trade and Development Canada / Ministère des Affaires étrangères, Commerce et Développement Canada

OTTAWA-CANADA

Signature: _____ Date: **2014-04-28**

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

VOID

2014

Health Canada Santé Canada

Canada

CONSULADO GENERAL DE COLOMBIA
TORONTO - CANADÁ
AUTENTICACIÓN DE FIRMA
El (La) Cónsul de Colombia
CERTIFICA

Que KAILEIGH RUSSELL, quien firma y otorga al presente documento, ejercita legalmente a la fecha ahí expresada el cargo de OFICIAL MINISTERIO RELACIONES EXTERIORES CANADA, y que la firma y sello en el documento aparecen como suyos, son los que usa y acostumbra en todos sus actos.

El Ministerio de Relaciones Exteriores de Colombia, no asume responsabilidad por el contenido del documento.

MINISTERIO DE RELACIONES EXTERIORES DE COLOMBIA
LUCIA MADRIÑAN SAA
CONSUL GENERAL
Firmado Digitalmente

Derechos	USD 27,00
FONDO ROTATORIO	USD 16,00
TIMBRE	USD 11,00

Fecha de Expedición: 04 junio 2014

Impresión No.: 1

La autenticidad de este documento puede ser verificada en: http://verificacion.cancilleria.gov.co.
Código de Verificación:AFOGE10732273

Explanatory Notes

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

01 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.

AFFIDAVIT

I, Neil Barkat, of the City of Ottawa, in the Province of Ontario, Public Servant, SOLEMNLY AFFIRM AND DECLARE AS FOLLOWS:

1. I have been employed by the federal government at Health Canada since September 7, 2004. I am currently acting as the Manager of the Establishment Licensing, Billing and Invoicing Unit, Inspectorate Ottawa, Health Products and Food Branch Inspectorate, Health Canada, and have held that position since November 25, 2013.

2. My duties as Manager of the Establishment Licensing, Billing and Invoicing Unit include the signing of Certificates of a Pharmaceutical Product conforming to the format recommended by the World Health Organization.

3. Reproduced immediately below is a copy of my employee identification card, number 54467B (Expiry 21/07/2014) issued by Health Canada:



SWORN BEFORE ME at the City of Ottawa, in the Province of Ontario, this 25th day of April, 2014.

Neil Barkat

Marylee Diane Dean, a Commissioner, etc.,
Province of Ontario, for the Government of Canada,
Department of Health.
Expires November 16, 2014.