The State of Texas

Secretary of State

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APOSTILLE

(Convention de La Haye du 5 Octobre 1961)

1. Country	**United States of America**
This public document	
2. has been signed by	**ALICE HERNANDEZ**
3. acting in the capacity of	**Notary Public, State of Texas**
4. and bears the seal/stamp of	**ALICE HERNANDEZ, Notary Public, State of Texas, Commission Expires: 05-21-20**

CERTIFIED

5. at Austin, Texas **6. on February 2, 2018**

7. by the Secretary of State of Texas

8. Certificate No. 11473918

9. Seal **10. Signature:**

Rolando B. Pablos
Secretary of State

GF/eg

EUROSTATION II
Place Victor Hortaplein 40/40
1060 BRUSSELS (BELGIUM)
http://www.fagg-afmps.be

Federal Agency for Medicines and Health Products

CERTIFICATE NUMBER: ***BE/GMP/2017/090***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Belgium confirms the following:
The manufacturer: ***ALCON LABORATORIES INC - ASPEX***
Site address: ***6201 SOUTH FREEWAY, SOUTH GATE, FORT WORTH, 76134-2099, United States***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 19(3) of Regulation 726/2004/EC .

Is an excipient manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-09-14*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]
- An appropriate level of GMP as referred to in Article 46(f) of Directive 2001/83/EC

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids Special Requirements 7 Other: Prostaglandines(en)
1.5	**Packaging**
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

2017-11-24

Name and signature of the authorised person of the Competent Authority of Belgium

Mr. Xavier De Cuyper
Federal Agency for Medicines and Health Products
Tel: *+32 2 5284000*
Fax: *+32 2 5284001*

State of Texas
County of Tarrant

On this 31 day of January, 2018,
I certify that the preceding document, and the duplicate retained by me as a notarial record, are true, exact, complete, and unaltered photocopies made by me of Certificate of GMP Compliance of a Manufacturer Alcon Laboratories, Inc. - ASPEX
presented to me by the document's custodian, Alcon Laboratories, and that, to the best of my knowledge, the photocopied document is neither a public record nor a publicly recordable document, certified copies of which are available from an official source other than a notary.

Alice Hernandez

AFMPS
FAGG

Agencia Nacional de Medicamentos y Productos Sanitarios

Certificado N°: BE/GMP/2017/090

CERTIFICADO DE CUMPLIMIENTO GMP DEL FABRICANTE

Parte 1

Emitido luego de una inspección en conformidad con:

Art. 111(5) de la Directiva 2001/83/EC modificado

La autoridad competente de Bélgica confirma lo siguiente:

El fabricante ***ALCON LABORATORIES INC - ASPEX***
Dirección planta ***6201 SOUTH FREEWAY, SOUTH GATE, FORT WORTH, 76134-2099, Estados Unidos***

Ha sido inspeccionado conforme al listado de fabricantes con autorización de comercialización ubicados fuera del Área Económica Europea de acuerdo con el Artículo 19(3) de la Normativa 726/2004/EC.

Es un fabricante de excipientes que ha sido inspeccionado de acuerdo al Artículo 111(1) de la Directiva 2001/83/EC.

De acuerdo a la información obtenida durante la inspección de este fabricante, la última realizada el **14 de septiembre de 2017**, se considera que cumple con:

- Los principios y pautas de Buenas Prácticas de Manufactura, incluidos en la Directiva 2003/94/EC.
- Un nivel apropiado de GMP como es indicado en el Artículo 46(f) de la Directiva 2001/83/EC.

Este certificado refleja el estado de la planta elaboradora al momento de la inspección indicada arriba y no se debe confiar en el estado de cumplimiento si han transcurrido más de tres años desde la fecha de dicha inspección. Sin embargo, este periodo de validez se podría reducir o ampliar usando principios de gestión de riesgo regulatorio mediante una anotación en el campo de comentarios Restricciones o Aclaraciones. Este certificado sólo es válido si presenta todas las páginas y las partes 1 y 2. La autenticidad de este certificado puede ser verificada en EudraGMDP. Si no aparece, favor contactar a la autoridad emisora.

Parte 2

Productos medicinales humanos

1 - OPERACIONES DE MANUFACTURA

1.1	**Productos estériles**
	1.1.1 Preparados en forma aséptica (operaciones de procesamiento para las siguientes formas farmacéuticas) 1.1.1.4 Líquidos de volumen pequeño Requerimientos especiales 7 Otros: prostaglandinas
1.5	**Envasado**
	1.5.2 Envasado secundario
1.6	**Pruebas de control de calidad**
	1.6.2 Microbiológico: no esterilidad 1.6.3 Químico/Físico

24 de noviembre de 2017

Nombre y firma de la persona autorizada
de la autoridad competente de Bélgica

Declaro que la traducción es fiel a la original,

Bernardita Garin
Director Técnico
Novartis Chile S.A.