APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country : United States of America
2. This public document has been signed by **HARDIKKUMAR PATEL**
3. acting in the capacity of NOTARY PUBLIC
4. bears the seal/stamp HARDIKKUMAR PATEL , NOTARY PUBLIC, BUCKS COUNTY, COMMONWEALTH OF PENNSYLVANIA

Certified

5. at Harrisburg, Pennsylvania
6. The 25th day of August, 2017
7. by Pedro A. Cortés, Secretary of the Commonwealth of Pennsylvania
8. No: 201724471
9. Seal/Stamp

10. Signature

Pedro A. Cortés

Pedro A. Cortés

This Apostille only certifies the authenticity of the signature and the capacity of the person who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears.

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Worldwide Research & Development

Worldwide Safety & Regulatory
Product License Support
Pfizer Internal Reference: 28098-45847

ATTESTATION

For Use in Chile

Re: Certificate of Good Manufacturing Practices (GMP):
Pharmacia and Upjohn Company LLC, 7000 Portage Road, Kalamazoo, Michigan (MI) 49001, United States (USA)

To Whom It May Concern:

I, Patricia Mehrman, Regulatory Affairs Product License Support Manager at Pfizer Inc, a corporation organized and existing under the laws of the State of Delaware, United States of America, with offices at 500 Arcola Road, Collegeville, Pennsylvania 19426, USA, hereby declare the attached to be a true and accurate document.

Patricia Mehrman

Patricia Mehrman
Product License Support Manager
Pfizer Inc

COMMONWEALTH OF PENNSYLVANIA
NOTARIAL SEAL
HARDIKKUMAR PATEL
Notary Public
BENSALEM TWP, BUCKS COUNTY
My Commission Expires Jun 30, 2020

UNITED STATES OF AMERICA)
COMMONWEALTH OF PENNSYLVANIA)
TOWNSHIP OF BENSALEM, BUCKS COUNTY)

Subscribed and sworn to before me this 22nd day of August 2017.

Notary

Hardikkumar Patel

853402

BLAIR CONSULAR SERVICES LTD

Federal Agency for Medicines and Health Products

CERTIFICATE NUMBER: ***BE/GMP/2016/001***

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: ***Pharmacia and Upjohn Company LLC***
Site address: ***7000 Portage Road, Kalamazoo, Michigan, 49001, 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 .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2016-10-14*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

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.

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[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)
	1.1.1.2 Lyophilisates
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms)
	1.2.1.6 Liquids for internal use
1.5	**Packaging**
	1.5.1 Primary Packing
	1.5.1.6 Liquids for internal use
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical

2017-01-20

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

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Confidential
Federal Agency for Medicines and Health Products
Tel: ***Confidential***
Fax: ***Confidential***