

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 18th day of August, 2017
7. by Pedro A. Cortés, Secretary of the Commonwealth of Pennsylvania
8. No: 201723675
9. Seal/Stamp
10. Signature



Pedro A. Cortés
Pedro A. Cortés

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Worldwide Research & Development

**Worldwide Regulatory
Product License Support**

Pfizer Internal Reference: 28005-45706

ATTESTATION

For Use in: Chile

Re: Certificate of Good Manufacturing Practices (GMP):

Hospira Inc., Highway 301 North, Rocky Mount 2226, North Carolina 27801

To Whom It May Concern:

I, Jared Hibbs, Regulatory Affairs Product License Support Manager at Pfizer Inc, a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 500 Arcola Road, Collegeville, Pennsylvania 19426, USA, hereby declare that attached hereto is a true and accurate copy of the document it purports to be.



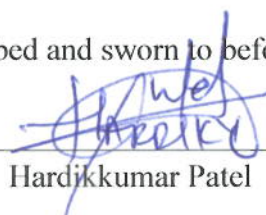
Jared Hibbs
Product License Support Manager
Pfizer Inc

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

COMMONWEALTH OF PENNSYLVANIA

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

Subscribed and sworn to before me this 15th day of August 2017.


Hardikkumar Patel

Notary

852264
BLAIR CONSULAR SERVICES LTD

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 Netherlands confirms the following:
The manufacturer: **Hospira Incorporation**
Site address: **Highway 301 North, Rocky Mount, North Carolina, 27801, 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 **2016-05-04** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC³

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 EudraGMP. 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 EudraGMP database.

³ These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.1	Sterile products
	1.1.2 <i>Terminally Sterilised (processing operations for the following dosage forms)</i> 1.1.2.3 Small volume liquids
1.6	Quality control testing
	1.6.1 <i>Microbiological: sterility</i> 1.6.2 <i>Microbiological: non-sterility</i> 1.6.3 <i>Chemical/Physical</i>

2016-05-17

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

Confidential
Health Care Inspectorate - Pharmaceutical Affairs and
Medical Technology
Tel: **Confidential**
Fax: **Confidential**