This Apostille is not valid for use anywhere within the United States of America, its territories or possessions.

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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Apostille

(Convention de La Haye du 5 octobre 1961)

1. District of Columbia, United States of America
2. This public document has been signed by KAMAL S. AHMAD
3. acting in the capacity of NOTARY PUBLIC IN AND FOR THE DISTRICT OF COLUMBIA
4. bears the seal/stamp of KAMAL S. AHMAD, NOTARY PUBLIC IN AND FOR THE DISTRICT OF COLUMBIA

CERTIFIED

5. at Washington, D.C.
6. the 6, day of DECEMBER 2018
7. by *Secretary of the District of Columbia*
8. No. 497567
9. Seal/Stamp
10. Signature:

Lauren C. Vaughan
Secretary of the District of Columbia

MSD

December 4, 2018

TRUE AND ACCURATE COPY DECLARATION

I, Deborah L. Gallagher, hereby certify the following attached document is a true and accurate copy:

- Eudra GMP Certificate Number NL/H 18/2008568 for Patheon Manufacturing Services located at 5900 Martin Luther King Jr. Highway, Greenville, North Carolina 27834, United States

Deborah L. Gallagher
Regulatory Affairs International

Commonwealth of Pennsylvania)
) SS:
County of Montgomery)

On this, the 4th day of December 2018, before me a notary public, the undersigned officer, personally appeared Deborah L. Gallagher, known to me (or satisfactorily proven) to be the person whose name is subscribed to the within instrument, and acknowledged that she executed the same for the purposes therein contained.

In witness whereof, I hereunto set my hand and official seal.

Notary Public

Commonwealth of Pennsylvania - Notary Seal
CHELSEA L. REINERT, Notary Public
Montgomery County
My Commission Expires February 23, 2022
Commission Number 1328117

Pr Proprietary

I Certify That This Is An
Original Document
Betty

District of Columbia: SS
Subscribed and sworn to before me,
this 6 day of Dec 2018

Kamal S. Ahmad, Notary Public, D.C.
My Commission expires December 14 2019

Health and Youth Care Inspectorate – Pharmaceutical Affairs

CERTIFICATE NUMBER: ***NL/H 18/2008568***

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
Art. 80(5) of Directive 2001/82/EC as amended

The competent authority of Netherlands confirms the following:
The manufacturer: ***Patheon Manufacturing Services LLC***
Site address: ***5900 Martin Luther King Jr. Highway, Greenville, NC 27834, United States***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC and Art. 80(4) of Directive 2001/82/EC transposed in the following national legislation:
Art. 100 of the Medicines Act

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2018-10-25*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]
- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/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 Veterinary Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.5 Liquids for external use
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.5 Liquids for external 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*

2018-11-22

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

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Confidential
Health and Youth Care Inspectorate – Pharmaceutical Affairs
Tel: ***Confidential***
Fax: ***Confidential***