SECRETARY OF STATE
STATE OF INDIANA

Connie Lawson
Secretary of State

APOSTILLE

(Conventions de la Haye du 5 Octobre 1961)

1. Country: United States of America
2. This public document has been signed by *Cameron L. Miller*
3. Acting in the capacity of notary public in & for *Boone County*
4. and bears the seal/stamp of certification clerk in & for Sec. of State Office

CERTIFIED

5. at Indianapolis, Indiana
6. This *Tenth* day of *April, 2018*
7. by the Secretary of State of Indiana
8. No. A2018–*0410123202*
9. Seal/Stamp:
10. Signature:

Connie Lawson

Connie Lawson
Indiana Secretary of State

Effective May 1, 2003 all apostilles from the Indiana Secretary of State will have an electronically printed seal.
This document was revised March 17, 2012.

Eli Lilly and Company

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

Date: 10 April 2018

To: Regulatory Authorities in Colombia

Re: Livalo® DP Inspection Report/Patheon Pharmaceuticals Inc.

To Whom It May Concern:

I, the undersigned, Virginia L. Blosser, Senior Specialist - Regulatory, attest that the attached Certificate of GMP Compliance of a Manufacturer for Patheon Pharmaceuticals Inc., 2110 East Galbraith Road, 45237, Cincinnati, Ohio, United States is a true copy of the original.

Respectfully,

ELI LILLY AND COMPANY

Virginia L. Blosser
Senior Specialist - Regulatory
Global Regulatory Affairs, CMC Submission Management

Subscribed and sworn to before me a Notary Public,

10 APRIL 2018
(Date)

(Notary Public – Signature)

CAMERON L MILLER
SEAL
NOTARY PUBLIC, STATE OF INDIANA
BOONE COUNTY
MY COMMISSION EXPIRES SEPTEMBER 10, 2023

Regierungspräsidium Darmstadt

CERTIFICATE NUMBER: *DE_HE_01_GMP_2017_0047*

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 Germany confirms the following:
The manufacturer: ***Patheon Pharmaceuticals INC.***
Site address: ***2110 East Galbraith Road, 45237, Cincinnati,Ohio, 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 .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2016-12-01*** , 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.

[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.*

EudraGMDP

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.13 Tablets
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

Any restrictions related to the scope of this certificate :

Building	Room	Line/equipment	QC testing	Products
				confidential

Clarifying remarks (for public users)

This certificate is in case of importation into the European Union only valid in connection with the current confirmation according to para 72a section 1 sentence 1 number 2 Medicinal Products Act, the German Drug Law (Arzneimittelgesetz AMG), issued to the importing company Warner Chilcott Deutschland GmbH, Dr.-Otto-Roehm-Strasse 2-4, 64331 Weiterstadt after the inspection according to para 72a section 1 sentence 2 number 1 Medicinal Products Act, and after confirming the validity of the inputs using the database according to para 67a Medicinal Products Act. This certificate is valid from 02.12.2016 to 01.12.2018.

2017-05-04

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

---

Confidential
Regierungspräsidium Darmstadt
Tel: ***Confidential***
Fax: ***Confidential***

EudraGMDP