Pharmaceutical Services
Patheon Pharmaceuticals Inc.
2110 East Galbraith Road
Cincinnati, Ohio 45237-1625 USA

May 15, 2020

Certificate of Good Manufacturing Practice for Patheon Pharmaceuticals Inc.

This certifies that Patheon Pharmaceuticals Inc. operates pharmaceutical manufacturing facilities located at 2110 East Galbraith Road, Cincinnati, Ohio 45237-1625 USA. The FDA Facility Establishment Identifier No. is 1510437. These facilities are operated in conformance to and regularly inspected for compliance with United States and European Union regulations governing Good Manufacturing Practices.

The most recent U.S. Food and Drug Administration cGMP general inspection of the Patheon Cincinnati facility was conducted over the period of January 6 – 14, 2020. The US FDA does not issue paper copies of Manufacturing Authorizations or GMP certificates after inspections. Attached is the cover letter from the Establishment Inspection Report for this general inspection.

Also attached is a true and correct copy of the 2020 U.S. Food and Drug Administration Annual Registration of Drug Establishment status for Patheon Pharmaceuticals Inc. This document was retrieved from the FDA Drug Establishments Current Registration Website. Verification of the registration may be performed at the following address:

http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm

A summary of recent FDA general inspections with the outcome classifications is attached. This summary was retrieved from the FDA Inspection Classification Database. Verification of this information may be performed at the following address:

https://www.accessdata.fda.gov/scripts/inspsearch/

The most recent European Medicines Agency coordinated GMP general inspection of the Patheon Cincinnati facility was conducted over the period of January 17 – 19, 2017.

I certify that the above is a true statement to the best of my knowledge and belief.

Lisa G. Gibson

Lisa G. Gibson
Site Quality Head
Patheon Pharmaceuticals Inc.
by Thermo Fisher Scientific
2110 East Galbraith Road
Cincinnati, Ohio 45237-1625 USA

513-948-7320
lisa.gibson1@thermofisher.com

Drug Establishments Current Registration Site

New Search

Search Results for **patheon pharmaceuticals inc**

CSV Excel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Patheon Pharmaceuticals Inc.	1510437	005286822	ANALYSIS; LABEL; MANUFACTURE; PACK;	2110 E Galbraith Rd., Cincinnati, Ohio (OH) 45237, United States (USA)	12/31/2020

Showing 1 to 1 of 1 entries

Previous 1 Next

Data Current through: Thursday, Nov 14, 2019

U.S. FOOD & DRUG ADMINISTRATION

PHARMACEUTICAL QUALITY INVESTIGATION BRANCH
300 River Place, 5th Floor
DETROIT, MI 48207
313-393-2027
www.fda.gov

Via UPS
Return Receipt Requested

02/14/2020

[redacted]
Vice President and General Manager
Patheon Pharmaceuticals, Inc.
2110 E. Galbraith Road
Cincinnati, OH 45237-1625
US

Dear [redacted]

The U.S. Food and Drug Administration (FDA) conducted an inspection at Patheon Pharmaceuticals Inc, FEI:1510437, located at 2110 E Galbraith Rd, Cincinnati, OH 45237-1625 US from 01/07/2020 - 01/14/2020. FDA has determined that the inspection classification of this facility is "no action indicated" ('NAI')[1]. Based on this inspection, this facility is considered to be in an acceptable state of compliance with regards to current good manufacturing practice (CGMP).

This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to ensure continued compliance with CGMP.

An inspection classification of NAI for CGMP compliance will not directly negatively impact FDA's assessment of any pending marketing application referencing this facility. Please note, however, that application approval will depend on a product- and application-specific facility assessment conducted by the appropriate CDER or CVM review office. This letter does not address or reflect FDA's decision making with respect to any potential non-CGMP compliance issues.

FDA has concluded that this inspection is "closed" under 21 CFR 20.64(d)(3), and we are enclosing a copy of the narrative portion of the Establishment Inspection Report (EIR). It may reflect redactions made by FDA in accordance with the Freedom of Information Act (FOIA) and 21 CFR part 20. This, however, does not preclude you from requesting additional information under FOIA.

If you have any questions regarding this letter, you may contact Steven Eastham via telephone at 513-246-4134 x1103 or email at Steven.Eastham@FDA.HHS.GOV.

Sincerely,

Graham T. Leslie -S

Digitally signed by Graham T. Leslie -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001372740, cn=Graham T. Leslie -S
Date: 2020.02.14 10:11:39 -05'00'

GRAHAM T. LESLIE
PROGRAM SUPPORT SPECIALIST
PHARMACEUTICAL QUALITY INVESTIGATION BRANCH

[1] See Inspection Classification Definitions, at https://www.fda.gov/ICECI/Inspections/ucm223231.htm.

Results: Inspection Classification Database Search

Search Again | Modify Search | Excel

More Information on Search Form Fields

Number of Records Displayed: 4
Number of Records Found: 4

1

District	Firm Name	City	State	Zip Code	Country / Area	Inspection End Date	Center	Project Area	Classification
CIN	Patheon Pharmaceuticals Inc	Cincinnati	OH	45237	US	01/14/20	CDER	Drug Quality Assurance	NAI
CIN	Patheon Pharmaceuticals Inc	Cincinnati	OH	45237	US	02/14/18	CDER	Drug Quality Assurance	VAI
CIN	Patheon Pharmaceuticals Inc	Cincinnati	OH	45237	US	03/11/16	CDER	Drug Quality Assurance	VAI
CIN	Patheon Pharmaceuticals Inc	Cincinnati	OH	45237	US	03/02/17	CDER	Drug Quality Assurance	VAI