



ODPIS

Chief Pharmaceutical Inspector

IWPS.405.89.2019.KK.1

WTC/0092_01_01/213

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC as amended

Chief Pharmaceutical Inspector

/the Competent Authority of Poland/

confirms the following:

the manufacturer and importer

GlaxoSmithKline Pharmaceuticals S.A.**ul. Grunwaldzka 189, 60-322 Poznań, POLAND**

site address

GlaxoSmithKline Pharmaceuticals S.A.**ul. Grunwaldzka 189, 60-322 Poznań, POLAND**

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **100/0092/15** in accordance with Art. 40 of Directive 2001/83/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2017, item 2211).

From the knowledge gained during inspection of this manufacturer and importer, the latest of which was conducted on **04-07/06/2019**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive 2003/94/EC.

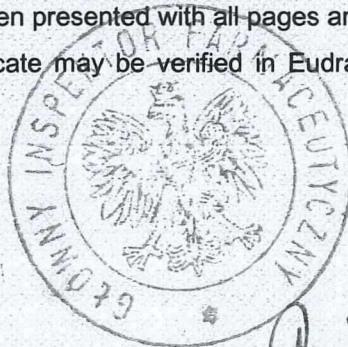
This certificate reflects the status of the manufacturing and importation site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced 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.

date: 2019 -09- 06

Chief Pharmaceutical Inspectorate
ul. Senatorska 12, 00-082 Warszawa, Poland
Tel. +48 22 635 99 51, fax. +48 22 635 99 57



Paweł Piotrowski
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Chief Pharmaceutical Inspector

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS

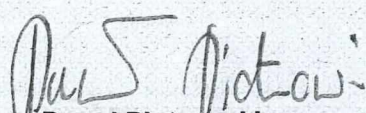
1.2	Non-sterile products
	1.2.1 Non-sterile products 1.2.1.8 Other solid dosage forms 1.2.1.13 Tablets 1.2.2 Batch certification
1.5	Packaging
	1.5.1 Primary packing 1.5.1.13 Tablets 1.5.2 Secondary packing
1.6	Quality control testing
	1.6.2 Microbiological: non sterility 1.6.3 Chemical/Physical 1.6.4 Biological

Any restrictions or clarifying remarks related to the scope of this certificate:

Points 1.2.1.13, 1.5.1.13 include also manufacturing of medicinal products containing: highly sensitising or highly potent or highly toxic or flammable substances or irritants.

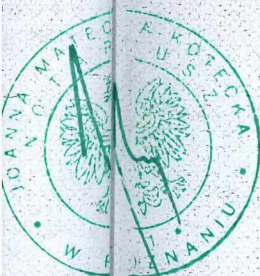
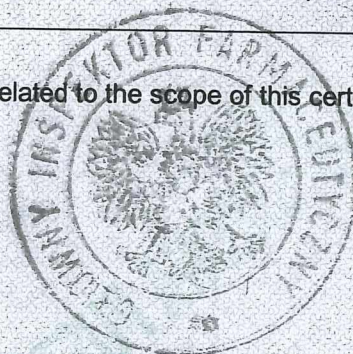
date: 2019 -09- 0 6

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Chief Pharmaceutical Inspector

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products
	2.1.2 Microbiological: non sterility 2.1.3 Chemical/Physical
2.2	Batch certification of imported medicinal products
	2.2.2 Non-sterile products
2.3	Other importation activities
	2.3.2 Importation of intermediate which undergoes further processing: tablets in-bulk or tablets in primary packaging 2.3.3 Other: storage of reference and retention samples

Any restrictions or clarifying remarks related to the scope of this certificate:



date: 2019 -09- 0 6

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JMK

KANCELARIA NOTARIALNA

JOANNA MATECKA-KOTECKA

ul. Wielka 12/2 61-774 Poznań
tel. kom. 783 96 96 72 tel. 61 22 37 097
jmkoteka@notarialnyakt.pl

NUMER REPERTORIUM A 5233/2019

Poświadcza się dosłowną zgodność niniejszego odpisu z okazanym dokumentem.-----

Pobrano: -----

a) wynagrodzenie z § 13 rozp. Ministra Sprawiedliwości z dnia 28 czerwca 2004r.
w sprawie maksymalnych stawek taksy notarialnej

(tekst jednolity Dz.U. z 2013 r. poz.237) 15,00 zł

b) podatek od towarów i usług VAT w stawce 23% od pozycji a) 3,45 zł

Razem: 18,45 zł

Słownie: osiemnaście i 45/100 złotych.-----

Poznań, dnia drugiego października dwa tysiące dziewiętnastego roku (02.10.2019r.).-



Joanna Matecka-Koteka
notariusz

Nr rej. 10911/19

Niniejszym stwierdzam autentyczność podpisu

Joanna Matecka-Koteka
notariusza

w Poznań i pieczęci urzędowej.

Oplata skarbową została uiszczona

w kwocie 26 zł. Słownie: dwadzieścia sześć

Poznań, dnia 18 października 2019r.

Jarosław Komorowski

Wiceprezes Sądu Okręgowego





APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. Państwo / *Country*: **Rzeczpospolita Polska**
Niniejszy dokument urzędowy / This public document
2. podpisany został przez
has been signed by **Jarosław Komorowski**
3. działającego w charakterze
acting in the capacity of **Prezes**
4. zaopatrzony jest w pieczęć/stempel
bears the seal/stamp of **Sąd Okręgowy w Poznaniu**

Poświadczony / *Certified*

5. w / at Warszawa
6. dnia / the **2019-10-30**
7. przez / by Ministerstwo Spraw Zagranicznych
8. Nr / N° **61217/2019**
9. Pieczęć/stempel
Seal/stamp:
10. Podpis:
Signature:

Tomasz Wasilewski
Referat ds. Legalizacji
DEPARTAMENT KONSULARNY

