CERTIFICATE No. GIF-IW-400/0092_01_03/04/77/15

POŚWIADCZONY ODPIS

Main Pharmaceutical Inspector

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

Main Pharmaceutical Inspector
/the Competent Authority of Poland/

confirms the following:

the manufacturer

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

site address

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

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **GIF-IW-400/0092/01/98/ZW32/15** in accordance with Art. 40 of Directive 2001/83/EC transposed in pharmaceutical law of 6th of September 2001 (Dz. U. z 2008 r. Nr 45, poz. 271, z późn. zm.).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **19-20/05/2015**, 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 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, after which time the issuing authority should be consulted.

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.

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

date: 2015 -08- 10

Main Pharmaceutical Inspectorate
12 Senatorska Street, 00-082 Warsaw, Poland
Tel. +48 22 635 99 51, fax. +48 22 635 99 57

Zofia Ulz
Main Pharmaceutical Inspector

CERTIFICATE No. GIF-IW-400/0092_01_03/04/77/15

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products
	1.2.1.1 Capsules, hard shell
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary packing
	1.5.1.1 Capsules, hard shell
	1.5.2 Secondary packing

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

date: 2015 -08- 10

Main Pharmaceutical Inspectorate
12 Senatorska Street, 00-082 Warsaw, Poland
Tel. +48 22 635 99 51, fax. +48 22 635 99 57

Zofia Ulz
Main Pharmaceutical Inspector

MAREK KOLASA
notariusz
PAWEŁ KOLASA
notariusz
SPÓŁKA CYWILNA
ul. Libelta 26
61-707 POZNAŃ
tel./fax. 061 8520996
tel. 061 8515871
tel. 061 8520961
kolasa@rejent.poznan.pl

Repertorium A nr 1479 **/2016**

Poświadczam zgodność powyższej kopii z okazanym dokumentem sporządzonym w języku angielskim. ----------

Pobrano: ----------

a) wynagrodzenie z § 13 pkt 2 Rozporządzenia Ministra Sprawiedliwości z dnia 28 czerwca 2004 roku (Dz.U.2013.237 j.t.) w sprawie maksymalnych stawek taksy notarialnej **6,00-zł**

b) podatek VAT (23%) zgodnie z art. 41 w zw. z art. 146 a ustawy o podatku od towarów i usług z dnia 11 marca 2004 roku (Dz.U.2011.177.1054 j.t.).**1,38-zł**

Razem:.....**7,38-zł**

Słownie: siedem złotych trzydzieści osiem groszy.----------

Poznań, dnia szesnastego lutego dwa tysiące szesnastego (**16.02.2016**) roku.---

Andrzej Kolasa
zastępca notarialny

Nr rej. 791/2017
Niniejszym stwierdzam autentyczność podpisu
Kolasa Andrzej - zastępca notarialny
~~notariusza~~
w Poznaniu i pieczęci urzędowej.
Opłata skarbowa została uiszczona
w kwocie 26,00 zł. Słownie: dwadzieścia sześć złotych
Poznań, dnia 01 sierpnia 2017r.

Piotr Majchrzak
Wiceprezes Sądu Okręgowego

RP

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 **Piotr Majchrzak**
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* **2017-08-07**
7. przez / by Ministerstwo Spraw Zagranicznych
8. Nr / *N°* **28514/2017**
9. Pieczęć/stempel
   Seal/stamp:
10. Podpis:
    Signature:

Krzysztof Augustyniak
Podreferendarz

MINISTERSTWO SPRAW ZAGRANICZNYCH

BE IT KNOWN that I, Sunita Kumeri of, 18-24 Stoke Road, Slough, Berkshire United Kingdom a duly authorised Notary Public

CERTIFY ONLY that Brian Michael Howes who is well known to me and who is duly authorised by GlaxoSmithKline ("the Company") to represent it in this matter has today caused the annexed Copy Certificate of GMP Compliance of a Manufacturer issued to GlaxoSmithKline Pharmaceuticals S.A. to be produced to me and that he has represented to me on behalf of the Company that the said document is a true copy of the original document.

SIGNED and sealed at 18-24 Stoke Road, Slough, Berkshire aforesaid on 2nd March 2017.

Sunita Kumeri
Notary Public
England and Wales

Protocol No. 8117

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: Pays / Pais:	United Kingdom of Great Britain and Northern Ireland
This public document Le présent acte public / El presente documento público	
2. Has been signed by a été signé par ha sido firmado por	Sunita Kumeri
3. Acting in the capacity of agissant en qualité de quien actúa en calidad de	Notary Public
4. Bears the seal / stamp of est revêtu du sceau / timbre de y está revestido del sello / timbre de	The Said Notary Public

Certified

Attesté / Certificado

5. at á / en	London	**6. the** le / el día	03 March 2017
7. by par / por	Her Majesty's Principal Secretary of State for Foreign and Commonwealth Affairs		
8. Number sous no / bajo el numero	APO-223759		
9. Seal / stamp Sceau / timbre Sello / timbre	FOREIGN AND COMMONWEALTH OFFICE LONDON	**10. Signature** Signature Firma	A. Khan

This Apostille is not to be used in the UK and only confirms the authenticity of the signature, seal or stamp on the attached UK public document. It does not confirm the authenticity of the underlying document. Apostilles attached to documents that have been photocopied and certified in the UK confirm the signature of the UK official who conducted the certification only. It does not authenticate either the signature on the original document or the contents of the original document in any way.

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CERTIFICATE No. GIF-IW-400/0092_01_01/04/27/17

Chief Pharmaceutical Inspector

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 2008, No. 45, item 271 with amendments).

From the knowledge gained during inspection of this manufacturer and importer, the latest of which was conducted on **15-18/11/2016**, 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.

acting Chief Pharmaceutical Inspector

Zbigniew Niewójt

date: 2017 -01- 20

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

Zbigniew Niewójt
Chief Pharmaceutical Inspector

CERTIFICATE No. GIF-IW-400/0092_01_01/04/27/17

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile Products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products 1.2.1.8 Other solid dosage forms: granules 1.2.1.13 Tablets **1.2.2 Batch certification**
1.3	**Biological medicinal products**
	1.3.2 Batch certification 1.3.2.2 Immunological products
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**

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

acting Chief Pharmaceutical Inspector

Zbigniew Niewójt

date: 2017 -01- 20

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

Zbigniew Niewójt
Chief Pharmaceutical Inspector

CERTIFICATE No. GIF-IW-400/0092_01_01/04/27/17

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.3	**Other importation activities**
	2.3.2 Importation of intermediate which undergoes further processing: tablets in-bulk or tablets in primary packaging

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 sensitizing or highly potent or highly toxic or flammable substances or irritants.

date: 2017 -01- 20

Acting Chief Pharmaceutical Inspector

Zbigniew Niewójt

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

Zbigniew Niewójt
Chief Pharmaceutical Inspector

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

CERTIFICATE No. GIF-IW-400/0092_01_04/04/28/17

Chief Pharmaceutical Inspector

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 15 of Directive 2001/20/EC as amended

Chief Pharmaceutical Inspector
/the Competent Authority of Poland/

confirms the following:

the manufacturer

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. 13 of Directive 2001/20/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2008, No. 45, item 271 with amendments).

From the knowledge gained during inspection of this manufacturer the latest of which was conducted on **15-18/11/2016**, 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 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

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GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

acting Chief Pharmaceutical Inspector

date: 2017 -01- 20

Zbigniew Niewójt

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

Zbigniew Niewójt
Chief Pharmaceutical Inspector

CERTIFICATE No. GIF-IW-400/0092_01_04/04/28/17

Part 2

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products 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**

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

acting Chief Pharmaceutical Inspector

Zbigniew Niewójt

date: 2017 -01- 20

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

Zbigniew Niewójt
Chief Pharmaceutical Inspector

APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. Państwo / *Country*: **Rzeczpospolita Polska**
   Niniejszy dokument urzędowy / *This public document*
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4. zaopatrzony jest w pieczęć/stempel
   bears the seal/stamp of **Sąd Okręgowy w Poznaniu**

Poświadczony / *Certified*

5. w / *at* Warszawa
6. dnia / *the* **2017-08-07**
7. przez / by Ministerstwo Spraw Zagranicznych
8. Nr / *N°* **28513/2017**
9. Pieczęć/stempel:
   Seal/stamp:
10. Podpis:
    Signature:

Krzysztof Augustyniak
Podreferendarz