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Ministero dell'Economia e delle Finanze
MARCA DA BOLLO
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IDENTIFICATIVO : 01161397065566
0 1 16 139706 556 6

Agenzia Italiana del Farmaco

AIFA

Certificate No: IT/71-2/H/2017

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

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

The competent authority of Italy confirms the following:
The manufacturer GLAXOSMITHKLINE MANUFACTURING S.P.A.
Site address VIA A. FLEMING, 2 - 37135 VERONA (VR)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 43/2017 dated 03/02/2017 in accordance with Art. 40 of Directive 2001/83/EC/ transposed in the following national legislation: D. Lvo 219/2006 Art. 50.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 12/16/2016, it is considered that it complies with the Good Manufacturing Practice requirements referred to in The principles and guidelines of Good Manufacturing Practice 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.
The authenticity of this certificate may be verified with the issuing authority.

AIFA: Italian Medicines Agency
GMP Inspections and Manufacturing Authorizations of Medicinal Products Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+390659784410 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 2559

PC
GMP

Agenzia Italiana del Farmaco

AIFA

Part 2

Name and address of the site: GLAXOSMITHKLINE MANUFACTURINGS.P.A. - VIA A. FLEMING, 2 , 37135 VERONA(VR)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.1	**Sterile Products**		
	1.1.1	*Aseptically prepared*	
		1.1.1.6	Other aseptically prepared products: Powders Special Requirements: B-lactam antibiotics
	1.1.3	*Batch certification*	
1.5	**Packaging**		
	1.5.2	*Secondary packing*	
1.6	**Quality control testing**		
	1.6.1	*Microbiological: sterility*	
	1.6.3	*Chemical/Physical*	
	1.6.4	*Biological*	

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations:

1.1.1.6 Other aseptically prepared products (Powders): Betalctamic antibiotics: cephalosporins. ;

1.6.4 Biological: Lal Test;

Agenzia Italiana del Farmaco

AIFA

Name and address of the site:	GLAXOSMITHKLINE MANUFACTURING S.P.A. - VIA A. FLEMING, 2 , 37135 VERONA(VR)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

1.1	**Sterile investigational medical products**	
	1.1.1	*Aseptically prepared*
	1.1.1.6	Other aseptically prepared products: powder Special Requirements: B-lactam antibiotics
1.6	**Quality control testing**	
	1.6.1	*Microbiological: sterility*
	1.6.3	*Chemical/Physical*
	1.6.4	*Biological*

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations:

1.1.1.6 Other aseptically prepared products (powder): Betalctamic antibiotics: cephalosporins;

1.6.4 Biological: Lal Test;

Rome, 05/02/2017

Name and signature of the authorised person of the Competent Authority of Republic of Italy

Dott. Renato Massimi
GMP Inspections and Manufacturing Authorizations of Medicinal Products Office

AIFA Italian Medicines Agency
GMP Inspections and Manufacturing Authorizations of Medicinal Products Office
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SIS : 2559

PC
GMP

Apostille

(Convention de La Haye du 5 octobre 1961)

1. Stato: Italia

Il presente atto pubblico

2. è stato firmato da: RIVA ELEONORA

3. operante in qualità di: FUNZIONARIO

4.è munito del sigillo/bollo di: COMUNE DI ROMA

5.in : Roma 6. 01 dicembre 2017

7.da: Prefettura di Roma – Ufficio Territoriale del Governo di Roma

8. col numero: 2947

9. Sigillo/bollo : Prefettura di Roma – Ufficio Territoriale del Governo di Roma

10. Firma

Funzionario Delegato

Antonella Sergio

Questa apostille certifica solo la qualità del firmatario e il sigillo/timbro che è stato apposto. Non certifica il contenuto del documento per il quale è stata rilasciata.

BE IT KNOWN that I, Sunita Kumeri of, 268 Bath Road, Slough, Berkshire United Kingdom a duly authorised Notary Public

CERTIFY that

1. The signature set and subscribed to the certificate at the foot of the first page of the copy document annexed hereto is genuine having been subscribed thereto by Zoe Bruce whose identity I the Notary attest and who is duly authorised by Pfizer Limited ("the Company") to represent them in this matter, and
2. Zoe Bruce has thereby certified on behalf of the company that Certificate of GMP Compliance of a Manufacturer issued to GlaxoSmithKline Manufacturing S.P.A annexed hereto is a true copy of the original document.

SIGNED and sealed at 268 Bath Road, Slough, Berkshire aforesaid on 30th April 2020.

Sunita Kumeri
Notary Public
England and Wales

Protocol No. 96/20

AK

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: Pays / País:	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: 04 May 2020
7. by par / por	Her Majesty's Principal Secretary of State for Foreign and Commonwealth Affairs
8. Number sous no / bajo el numero	APO-1901742
9. Seal / stamp Sceau / timbre Sello / timbre	**10. Signature** O. Mardlin Signature Firma

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.

If this document is to be used in a country not party to the Hague Convention of the 5th of October 1961, it should be presented to the consular section of the mission representing that country

To verify this apostille go to www.verifyapostille.service.gov.uk

Italian Medicines Agency

CERTIFICATE NUMBER: ***IT/109/H/2019***

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 Italy confirms the following:
The manufacturer: ***GLAXOSMITHKLINE MANUFACTURING S.P.A.***
Site address: ***VIA A. FLEMING, 2, VERONA (VR), 37135, Italy***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***aM74/2019*** in accordance with Art. 40 of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-04-19*** , 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.

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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

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.6 Other: Other aseptically prepared products: Powders(en) Special Requirements 1 B-lactam Antibiotics
	1.1.3 Batch certification
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.3 Chemical/Physical* *1.6.4 Biological*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products

Clarifying remarks (for public users)

1.1.1.6 Other aseptically prepared products (Powders): Betalctamic antibiotics: cephalosporins. ; 1.6.4 Biological: Lal Test; 2.2.2 Non-sterile products: tablets and granules for oral suspension containing beta-lactams antibiotics (cephalosporins).

2019-05-30

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

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Confidential
Italian Medicines Agency
Tel: ***Confidential***
Fax ***Confidential***

Agenzia Italiana del Farmaco

CERTIFICATE NUMBER: ***IT/109/H/2019***

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

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Site address: ***VIA A. FLEMING, 2, VERONA (VR), 37135, Italy***

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2019-05-30

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

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Italian Medicines Agency
Tel: ***Confidential***
Fax: ***Confidential***