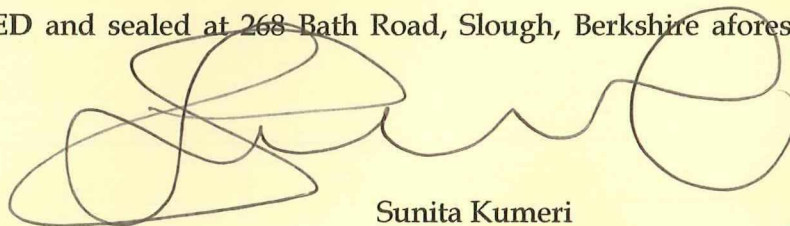




BE IT KNOWN that I, Sunita Kumeri of, 268 Bath Road, Slough, Berkshire United Kingdom a duly authorised Notary Public

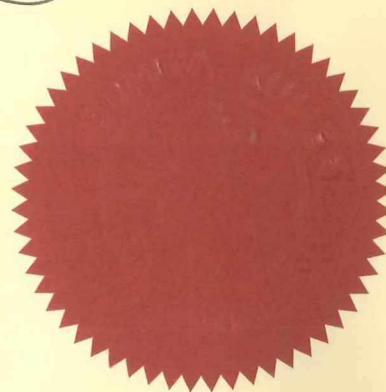
CERTIFY ONLY that Brian Michael Howes who is well known to me and who is duly authorised by GlaxoSmithKline ("the Company") to represent them in this matter has today caused the annexed Certificate of GMP Compliance of a Manufacturer issued to Glaxo Operations UK Ltd trading as Glaxo Wellcome Operations to be produced to me and has represented to me on behalf of the company that the said document is a true copy of the original electronic document produced to him.

SIGNED and sealed at 268 Bath Road, Slough, Berkshire aforesaid on 8th January 2020.



Sunita Kumeri
Notary Public
England and Wales

Protocol No. 12/20



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 à / en	London	6. the le / el día
		09 January 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-1788564	
9. Seal / stamp Sceau / timbre Sello / timbre		
	10. Signature Signature Firma	A. Hodges 

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



Medicines & Healthcare products
Regulatory Agency



Certificate No: UK MIA 4 Insp GMP/IMP 4/3848-0037

Medicines and Healthcare products Regulatory Agency

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 the United Kingdom confirms the following:

The manufacturer	GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS
Site address	HARMIRE ROAD BARNARD CASTLE DL12 8DT UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. MIA 4 in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation: The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 21/01/2019, it is considered that it complies with 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. 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 only valid 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.





Certificate No: UK MIA 4 Insp GMP/IMP 4/3848-0037

Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS

1.1 Sterile products

1.1.1 Aseptically prepared (processing operations for the following dosage forms)

1.1.1.1 Large volume liquids

1.1.1.4 Small volume liquids

1.1.2 Terminally sterilised (processing operations for the following dosage forms)

1.1.2.1 Large volume liquids

1.1.2.3 Small volume liquids

Special Requirements:

Other

Cytotoxic products

1.2 Non-sterile products

1.2.1 Non-sterile products (processing operations for the following dosage forms)

1.2.1.5 Liquids for external use

1.2.1.6 Liquids for internal use

1.2.1.8 Other solid dosage forms

Special Requirements:

Other

Cephalosporins

1.2.1.11 Semi-solids

1.2.1.13 Tablets

Special Requirements:

Other

Cephalosporins

1.2.1.17 Other non-sterile medicinal products

Not specified

1.2.2 Batch Certification

1.3 Biological medicinal products

1.3.1 Biological medicinal products

1.3.1.2 Immunological products

1.3.1.5 Biotechnology products

1.3.1.6 Human or animal extracted products

1.3.1.8 Other biological medicinal products

Steroids, Antibacterial Agents, Antifungal Agents

1.3.2 Batch certification (list of product types)



1.3.2.5 Biotechnology products

1.4 Other products or manufacturing activity

1.4.2 Sterilisation of active substances/excipients/finished product

1.4.2.1 Filtration

1.4.2.2 Dry heat

1.4.2.3 Moist heat

1.5 Packaging

1.5.2 Secondary packaging

1.6 Quality control testing

1.6.1 Microbiological: sterility

1.6.2 Microbiological: non-sterility

1.6.3 Chemical/physical

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

2.1.1 Microbiological: sterility

2.1.2 Microbiological: non-sterility

2.1.3 Chemical/physical

2.2 Batch certification of imported medicinal products

2.2.1 Sterile Products

2.2.1.1 Aseptically prepared products

2.2.1.2 Terminally sterilised products

2.2.2 Non-sterile products

2.3 Other importation activities

Not Authorised





Certificate No: UK MIA 4 Insp GMP/IMP 4/3848-0037

3. MANUFACTURING OPERATIONS

- 3.1 Manufacture of Active Substance by Chemical Synthesis**
Not Authorised
- 3.2 Processing Activities of Active Substance from Natural Sources**
Not Authorised
- 3.3 Manufacture of Active Substance using Biological Processes**
Not Authorised
- 3.4 Manufacture of sterile active substance**
Not Authorised
- 3.5 General Finishing Steps**
Not Authorised
- 3.6 Quality Control Testing**
Not Authorised
- 4 Other Activities**
Not Authorised





Certificate No: UK MIA 4 Insp GMP/IMP 4/3848-0037

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

N/A

1. Building(s)/Area(s)

N/A

2. Room(s)

N/A

3. Line(s) Equipment(s)

N/A

4. QC testing

N/A

5. Medicinal Product(s)/IMP(s)

N/A

**Name of the authorised person of the
Competent Authority of the United Kingdom**

Dr A J Gray
Head of Inspectorate
inspectionplanning@mhra.gov.uk

Date: 11/03/2019

