

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 Nextpharma SAS 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. 9120

APOSTILLE (Convention de La Haye du 5 octobre 1961) Country: United Kingdom of Great Britain and Northern Ireland Pays / Pais: This public document Le présent acte public / El presente documento público Has been signed by Sunita Kumeri a été signé par ha sido firmado por Acting in the capacity of **Notary Public** agissant en qualité de quien actúa en calidad de Bears the seal / stamp of The Said Notary Public est revêtu du sceau / timbre de y está revestido del sello / timbre de Certified Attesté / Certificado 5. at 6. the London 09 January 2020 le / el día á/en Her Majesty's Principal Secretary of State by par / por for Foreign and Commonwealth Affairs Number APO-1788563 sous no / bajo el numero Seal / stamp A. Hodges 10. Signature Sceau / timbre Signature Sello / timbre Firma

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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

French National Agency for Medicines and Health Products Safety

CERTIFICATE NUMBER: 2019/HPF/FR/290

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

The competent authority of France confirms the following:

The manufacturer: NEXTPHARMA SAS

Site address: 17 route de Meulan, LIMAY, 78520, France

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. MM 16/214 in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:

Art. L.5124-3 of Public Health Code

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 2019-07-19, it is considered that it complies with:

The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC³

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.

Signatory: Confidential

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

1.2	Non-sterile products	
	1.2.1 Non-sterile products (processing operations for the following dosage forms)	
	1.2.1.1 Capsules, hard shell	
	1.2.1.5 Liquids for external use	
	1.2.1.6 Liquids for internal use	
	1.2.1.9 Pressurised preparations	
	1.2.1.11 Semi-solids	
	1.2.1.12 Suppositories	
	1.2.2 Batch certification	
1.5	Packaging 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
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	1.5.1 Primary Packing	
	1.5.1.1 Capsules, hard shell	
	1.5.1.1 Capsules, hard shell 1.5.1.5 Liquids for external use	
	1.5.1.1 Capsules, hard shell1.5.1.5 Liquids for external use1.5.1.6 Liquids for internal use	
	1.5.1.1 Capsules, hard shell 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.9 Pressurised preparations	
	1.5.1.1 Capsules, hard shell 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.9 Pressurised preparations 1.5.1.11 Semi-solids	
	1.5.1.1 Capsules, hard shell 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.9 Pressurised preparations 1.5.1.11 Semi-solids	
	1.5.1.1 Capsules, hard shell 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.9 Pressurised preparations 1.5.1.11 Semi-solids 1.5.1.12 Suppositories	
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1.6	1.5.1.1 Capsules, hard shell 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.9 Pressurised preparations 1.5.1.11 Semi-solids 1.5.1.12 Suppositories 1.5.2 Secondary packing	4276 42 45

Clarifying remarks (for public users)

Signatory: Mr Said Ioughlissen, deputy head of the pharmaceutical product inspection and counterfeiting fight department --- The ANSM does not issue paper copies of good manufacturing practice certificates.

2019-10-23

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

Confidential

French National Agency for Medicines and Health

Products Safety
Tel: Confidential
Fax: Confidential