EXPRESS WORLDWIDE **DOX** DHL

2022-01-24 MYDHL+ 1.0 / "30-0821"

From : Blair Consular Services
SAMANTHA HIGGINSON
Elizabeth House
28 Woodthorpe Road

TW15 2RH ASHFORD
United Kingdom

Origin:
LHR

To : PFIZER CHILE SA
OSWBERLIS CALZADILLA
CERRO EL PLOMO 5680,
TORRE 6, PISO 16
LAS CONDES
SANTIAGO SANTIAGO
Chile

Contact:
OSWBERLIS CALZADILLA

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Day Time

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Contents: Documents - gen eral business

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Nikita Harika

From: Hakobyan, Edita <Edita.Hakobyan@pfizer.com>
Sent: 18 January 2022 09:29
To: Pfizer International
Cc: CALZADILLA, OSWBERLIS
Subject: PDF Legalization/18Jan/ 55733-109299
Attachments: GMP Certifikat Pfizer Health AB 5.9.1-2021-033386.pdf

Categories: Requets

Dear Blair Team,

Could you please organize the required legalization?

Kindly find the information below.

Recipient Country	Document Type (CPP, GMP etc)	Business Unit	Product Name	Authentication Required	Country of Authentication	Date Required by	Pfizer Ref No (please quote on invoice)	Recipient Details (Name, Address, T Email)
Chilie	GMP	PBG	Dalteparin sodium	Apostille	UK	18-Feb-22	55733-109299	**Recipient Name:** Oswberlis Calzadil **Recipient Email:** OSWBERLIS.CALZADILLA@PFIZI **Recipient Address:** CERRO EL PL(PISO 16, LAS CONDES, SANTIAGC

BE IT KNOWN that I Laura Anne Pawley, Mezzanine Floor, Epsom Square, Epsom, Surrey, KT19 8AG, a duly authorised Notary Public, duly admitted, sworn and practice throughout England and Wales.

CERTIFY ONLY that Nikita Kaur Harika, a United Kingdom Citizen, who is well known to me, who, is duly authorised by Pfizer Ltd to represent them in this matter, has today caused the annexed Certificate of GMP Compliance of a Manufacturer for Pfizer Health AB for use in Chile to be produced to me and that they have represented to me on behalf of the Company that the said document is a true electronic copy of the original document.

SIGNED and sealed at Mezzanine Floor, Epsom Square, Epsom, Surrey, KT19 8AG on the 18th of January 2022.

Protocol No: 2022-352

Laura Anne Pawley

Laura Anne Pawley
Notary Public

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	Laura Anne Pawley
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 21 January 2022
7.	**by** par / por	Her Majesty's Principal Secretary of State for Foreign, Commonwealth and Development Affairs	
8.	**Number** sous no / bajo el numero	APO-2791400	
9.	**Seal / stamp** Sceau / timbre Sello / timbre	10.	**Signature** N. Major Signature Firma

FOREIGN, COMMONWEALTH & DEVELOPMENT OFFICE LONDON

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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LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Medical Products Agency

CERTIFICATE NUMBER : ***5.9.1-2021-033386***

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 Sweden confirms the following:
The manufacturer :***Pfizer Health AB***
Site address :***Mariefredsvägen 37, Strängnäs, 645 41, Sweden***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***5.9.1-2020-072018*** in accordance with Art. 40 of Directive 2001/83/EC .

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-10-13*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]
- The principles of GMP for active substances [3] referred to in Article 47 of Directive 2001/83/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 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.*

LÄKEMEDELSVERKET · SWEDISH MEDICAL PRODUCTS AGENCY ·

Part 2

1 MANUFACTURING OPERATIONS	
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.5 Biotechnology products 1.3.1.8 Other: Cellbank(en)
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical* *1.6.4 Biological*

Manufacture of active substance. Names of substances subject to inspection :
ANAKINRA(en)
DALTEPARIN SODIUM(en)
SOMATROPIN(en)
B2036 INTERMEDIATE(en)
TRUMENBA(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES	
Active Substance :ANAKINRA	
3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.1 Fermentation
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing 3.6.4 Biological Testing
Active Substance :DALTEPARIN SODIUM	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Milling and drying 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**

Part 2

1 MANUFACTURING OPERATIONS	
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.5 Biotechnology products 1.3.1.8 Other: Cellbank(en)
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	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical* *1.6.4 Biological*

Manufacture of active substance. Names of substances subject to inspection :
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DALTEPARIN SODIUM(en)
SOMATROPIN(en)
B2036 INTERMEDIATE(en)
TRUMENBA(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES	
Active Substance :ANAKINRA	
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3.6	**Quality Control Testing**

	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
Active Substance :SOMATROPIN	
3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.1 Fermentation
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing 3.6.4 Biological Testing
Active Substance :B2036 INTERMEDIATE	
3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.1 Fermentation
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing 3.6.4 Biological Testing
Active Substance :TRUMENBA	
3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.1 Fermentation
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing 3.6.4 Biological Testing

Clarifying remarks (for public users)

1.3.1.5 Manufacturing of biotech drug substances and intermediates based on recombinant bacterial products or polysaccharide. (Tillverkning av bioteknologiska aktiva substanser och intermediat baserade på rekombinanta bakteriella produkter eller polysackarider.) 1.3.1.8 Manufacturing and storage of cellbank. (Tillverkning och förvaring av cellbank.)

2021-06-09

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

LÄKEMEDELSVERKET · SWEDISH MEDICAL PRODUCTS AGENCY ·

Mr. Bengt Berglund
Medical Products Agency
Tel:***+46 18 174600***
Fax:***+46 18 548566***