Health Products Regulatory Authority

CERTIFICATE NUMBER: ***34169/IMP11510/00001***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with
Art. 63 of Regulation (EU) 536/2014

The competent authority of Ireland confirms the following:
The manufacturer: ***Pfizer Ireland Pharmaceuticals***
Site address: ***Grange Castle Business Park, Clondalkin, Dublin 22, Ireland***
OMS Organisation Id. / OMS Location Id.: ***ORG-100001392 / LOC-100001621***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***IMP11510/00001*** in accordance with Art. 61 of Regulation (EU) No 536/2014.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-12-15***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.[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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). 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 Art. 15 of Directive 2001/20/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids
	1.1.3 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.2 Immunological products 1.3.1.5 Biotechnology products
	1.3.2 Batch Certification (list of product types) 1.3.2.2 Immunological products
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical* *1.6.4 Biological*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility *2.1.2 Microbiological: non-sterility* *2.1.3 Chemical/Physical* *2.1.4 Biological*

Clarifying remarks (for public users)

1.1.1.4 relates to manufacture of pre-filled syringes. 1.3.1.2 relates to manufacture of low bioburden vaccine conjugates, formulated bulk and final dosage form (pre-filled syringe). It also includes manufacture of mRNA based drug substance synthesized from linearised plasmid DNA via in vitro transcription. 1.3.1.5 relates to manufacture of biological active substance using mammalian cell technology its isolation / purification and formulation as a low bioburden bulk. The HPRA does not routinely issue hard copies of GMP certificates. Authenticity of GMP certification may be verified on the EudraGMDP database.

2024-03-01

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

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Health Products Regulatory Authority
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