HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Health Products Regulatory Authority

CERTIFICATE NUMBER: ***26079/M1063***

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 Ireland confirms the following:
The manufacturer: ***Pfizer Ireland Pharmaceuticals***
Site address: ***Little Connell, Newbridge, Co. Kildare, Ireland***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***1063*** in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:
Medicinal Products (Control of Manufacture) Regulations 2007 to 2013.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-09-27*** , 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.*

I certify that that this document is a true and faithful copy of the original document or of the relevant extracts thereto produced to me and which after careful examination I attest
this 22 day of January 2020

Hugh McGroddy, Notary Public,
33 Upper Merrion St., Dublin 2.
Commissioned for Life

HUGH Mc GRODDY
33 Upper Merrion Street
Dublin 2.
Notary Public for the
County and City of Dublin
Commissioned for Life

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Hugh McGroddy N.P.

APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. Country: Pays/País:	**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	Hugh McGroddy
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	Notary Public

Certified
Attesté / Certificado

5. at à / en	Dublin	**6. the** le / el día	22/01/2020
7. by par / por	Department of Foreign Affairs and Trade		
8. No sous no bajo el número	3622902020		
9. Seal / stamp: Sceau / timbre: Sello / timbre:	**10. Signature:** Signature: Firma:		

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Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
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 1.2.1.13 Tablets
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

Manufacturing operations include the manufacture of products with hormonal activity. 1.2.1.13 includes Real Time Release Testing on tablets. Assay and content uniformity using at-line Near Infrared (NIR) analysis. Any real time release testing must also be approved via specific Marketing Authorisation(s) for the product(s) concerned.

2019-12-19

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

CERTIFIED HPRA

Mr. Richard O'Sullivan
Health Products Regulatory Authority
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Fax:

Hugh McGroddy N.P.