Colombie 16352

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Health Products Regulatory Authority

CERTIFICATE NUMBER: *15483/M68*

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: ***Servier (Ireland) Industries Ltd***
Site address: ***Moneylands, Gorey Road, Arklow, Co. Wicklow, Ireland***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***68*** 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 ***2017-03-23*** , 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.

[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.*

FERGUS N.P. KINSELLA

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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) 1.2.1.13 Tablets
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packing 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*

2017-06-20

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

CERTIFIED HPRA
Ciara Turley

Ciara Turley
Health Products Regulatory Authority
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I hereby certify that the within document is a true copy of the document produced to me and described as a Certificate of GMP Compliance of a Manufacturer which it has been compared while in my possession.

Dated this 11th day of January 2018

Fergus Kinsella
Wexford Road,
Arklow, Co. Wicklow,
Ireland,
Notary Public
Commissioned for Life

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	Fergus Kinsella
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	--------

Certified
Attesté / Certificado

5. at à / en	Dublin	**6. the** le / el día	16/01/2018
7. by par / por	Department of Foreign Affairs and Trade		
8. No sous no bajo el número	0050122018		
9. Seal / stamp: Sceau / timbre: Sello / timbre:	**10. Signature:** Signature: Firma:		

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