BE IT KNOWN that I, Sunita Kumeri of, 18-24 Stoke Road, Slough, Berkshire United Kingdom a duly authorised Notary Public

CERTIFY that

1. The signature set and subscribed to the certificate at the foot of the first page of the copy document annexed hereto is genuine having been subscribed thereto by Zoe Bruce whose identity I the Notary attest and who is duly authorised by Pfizer Limited ("the Company") to represent them in this matter, and
2. Zoe Bruce has thereby certified on behalf of the Company that the copy Certificate of GMP Compliance of a Manufacturer issued to Fermion Oy annexed hereto is a true copy of the original document.

SIGNED and sealed at 18-24 Stoke Road, Slough, Berkshire aforesaid on 2nd August 2017.

Sunita Kumeri
Notary Public
England and Wales

Protocol No. 37/17

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	Sunita Kumeri
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: 04 August 2017
7. **by** par / por	Her Majesty's Principal Secretary of State for Foreign and Commonwealth Affairs
8. **Number** sous no / bajo el numero	APO-475853
9. **Seal / stamp** Sceau / timbre / Sello / timbre	10. **Signature** J. Horne Signature / Firma

FOREIGN AND COMMONWEALTH 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.

If this document is to be used in a country not party to the Hague Convention of the 5th of Octob[illegible] 1961 [illegible]

fimea

Certificate No: 2900/06.08.02.04/2017

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 or Art. 80(5) of Directive 2001/82/EC as amended and Art. 15 of Directive 2001/20/EC

The competent authority of Finland confirms the following:

The manufacturer: Fermion Oy

Site address: Lääketehtaantie 2, Oulu, FI-90660, Finland

Has been inspected under national inspection programme in connection with manufacturing authorisation no. 1301/06.08.00.04/2017 in accordance with Art. 40 of Directive 2001/83/EC, Art. 44 of Directive 2001/82/EC and Art. 13 of Directive 2001/20/EC transposed in the following national legislation: Medicines Act and Medicines Decree, Finland

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC and Art. 80(1) of Directive 2001/82/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 22nd April 2017, 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 and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EC[3] and The principles of GMP for active substances[3] referred to in Article 47 of Directive 2001/83/EC/ Article 51 of Directive 2001/82/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 and validity of this certificate should be verified in EudraGMDP database eudragmp.ema.europa.eu. If it does not appear, please contact issuing authority.

Turku 4th May 2017

Kari Lönnberg, Senior Inspector,
Finnish Medicines Agency, Inspectorate,
Tel. +358 29 522 3232, Fax. +358 29 522 3007

[1] The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, is also applicable to importers.
[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 ☒ Veterinary Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of: 1.4.1.3 Other: Non-sterile Active Starting materials: Aripiprazole, Atipamezole hycrochloride, Azathioprine, Benserazidine, Calsium folinate, Carbamazepine dihydrate, Detomidine hydrochloride, Dexmedetomidine hydrochloride, Formoterol fumarate, Irinotecan, Irinotecan HCl, (SN-38), Levosimendan, Medetomidine hydrochloride, 6-mercaptopurine, Methotrexate, Methotrexate (PTER-7) Methotrexate disodium, Nadolol, Ospemifene, Quetiapine fumarate, Pralatrexate, Salmeterol xinafoate, Tamsulosin, Toremifene citrate, Trazodone hydrochloride.
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of this certificate: This certificate is requested by Fermion Oy

Turku 4th May 2017

Kari Lönnberg, Senior Inspector,
Finnish Medicines Agency, Inspectorate
Tel. +358 29 522 3232, Fax. +358 29 522 3007

Proceeding fee MSAH 210/2016