RF AZ Shell Cambridge

AstraZeneca

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TO WHOM IT MAY CONCERN

Good Manufacturing Practice Certificate

It is hereby confirmed that the attached Certificate is a true copy of the original document.

Signed: ..... Dated 4/5/18

Vicky Beattie
Regulatory Project Assistant
Regulatory Project Management Group
AstraZeneca UK Limited

Signature Attested by Phillip Jones
Solicitor and Notary
Windsor House, Victoria Street,
Windsor, Berks, SL4 1EN, England,
Tel: 01753 851591

8/5/18.

7 5 9/18

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	Phillip H Jones
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: 17 May 2018
7. **by** par / por	Her Majesty's Principal Secretary of State for Foreign and Commonwealth Affairs
8. **Number** sous no / bajo el numero	APO-887471
9. **Seal / stamp** Sceau / timbre Sello / timbre	10. **Signature** Signature Firma: A. Hodges

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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Certificate No: 2239/06.08.00.04/2018

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.

The competent authority of Finland confirms the following:

The manufacturer: PCAS Finland Oy

Site address: Messukentänkatu 8, 20210 Turku, Finland

Has been inspected under national inspection programme in connection with manufacturing authorisation no. 5486/06.08.00.04/2017 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 14th-15th February 2018, 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 26th March 2018

Kari Lönnberg, Senior Inspector,
Finnish Medicines Agency, Inspectorate
Tel. +358 29 522 3341, 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 EudraGMP 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: 1.4.1.4 Others: Manufacture of non-sterile solid, powder or liquid Active substances: Apraclonidine HCl, Articaine HCl, Baclofen, Carprofen, Ciclopirox, Ciclopirox Olamine, Cinacalcet HCl, Clonidine, Clonidine HCl, Desipramine HCl, Disopyramide Phosphate, Dorzolamide HCl, Esomeprazole Sodium, Felodipine, Glycopyrrolate, , Mepivacaine HCl, Methenamine Hippurate, Olopatadine HCl, Oxybutynin HCl, Promazine HCl, R-Baclofen, Ropinirole, Ropinirole HCl, Tamoxifen Citrate, Tazarotene, Tetrahydrozoline HCl, Timolol Hemihydrate, Timolol Maleate, Custom manufacturing, Generic.
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of this certificate

Turku 26th March 2018

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☒ Human Investigational Medicinal products

1. Manufacturing operations	
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.4 Other
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of this certificate

The authorization covers also the manufacturing of active pharmaceutical ingredient for veterinary investigational medicinal products.

This certificate is requested by PCAS Finland Oy for EU.

Turku 26th March 2018.

Kari Lönnberg, Senior Inspector,
Finnish Medicines Agency, Inspectorate
Tel. +358 29 522 3341, Fax. +358 29 522 3007

Proceeding fee, MSAH 178/2017, PCAS Finland Oy