

Chile

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

Dated 10/1/18


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

AstraZeneca UK Limited is a subsidiary of AstraZeneca PLC
Registered in England No. 3674842
Registered office: 1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge, CB2 0AA
United Kingdom

72/18

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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 à / en	London
6. the le / el día	17 January 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-697581
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Medical Products Agency

CERTIFICATE NUMBER: 5.9.1-2017-096501

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

Art. 15 of Directive 2001/20/EC

The competent authority of Sweden confirms the following:

The manufacturer: **AstraZeneca AB**

Site address: **PET Turbuhaler and Pumpspray, Forskargatan 18, Södertälje, 151 85, Sweden**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **5.9.1-2017-050356** in accordance with Art. 40 of Directive 2001/83/EC and Art. 13 of Directive 2001/20/EC .

Other :

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2017-06-14** , 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.



Part 2

Human Medicinal Products
Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use 1.2.1.17 Other: multidose powder inhaler(en)
	<i>1.2.2 Batch certification</i>
1.5	Packaging
	<i>1.5.1 Primary Packing</i> 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.17 Other non-sterile medicinal products: multidose powder inhaler(en)
	<i>1.5.2 Secondary packing</i>
1.6	Quality control testing
	<i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i>

Manufacture of active substance. Names of substances subject to inspection :

BUDESONIDE(en)

FORMOTEROL(en)

TERBUTALINE SULPHATE(en)

GLYCOPYRRONIUM BROMIDE(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES	
Active Substance : BUDESONIDE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.4 Other : micronisation
Active Substance : FORMOTEROL	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.4 Other : micronisation
Active Substance : TERBUTALINE SULPHATE	



3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.4 Other : micronisation
Active Substance : GLYCOPYRRONIUM BROMIDE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.4 Other : micronisation

Clarifying remarks (for public users)

Manufacturing of drug substances for powder inhaler and other dosage forms. (Substansbearbetning för pulverinhalatorer och andra läkemedelsformer.) Manufacturing of porous particles. (Tillverkning av porösa partiklar.) Storage of active substance, excipients and packaging material can also be done at Gärtunavägen, Södertälje. (Förvaring av aktiv substans, hjälpämnen och förpackningsmaterial får även ske på Gärtunavägen, Södertälje.) QC analysis can be done at address Forskargatan 18 and Gärtunavägen, Södertälje. (Analys får utföras på Forskargatan 18 och Gärtunavägen, Södertälje.)

2017-12-28

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

Bengt Berglund

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Medical Products Agency
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