AZ 7372
Chile

AstraZeneca UK Limited
1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge, CB2 0AA
United Kingdom
T: +44 (0) 20 3749 5000

astrazeneca.com

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 30/1/20.....
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

3/2/2020

21/4/20

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: 04 February 2020
7. by par / por	Her Majesty's Principal Secretary of State for Foreign and Commonwealth Affairs
8. Number sous no / bajo el numero	APO-1825267
9. Seal / stamp Sceau / timbre Sello / timbre	**10. Signature** Signature Firma: J. Dutta

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 October 1961, it should be presented to the consular section of the mission representing that country

To verify this apostille go to www.verifyapostille.service.gov.uk

LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Medical Products Agency

CERTIFICATE NUMBER: ***6.2.1-2019-064369***

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 Sweden confirms the following:
The manufacturer: ***AstraZeneca AB***
Site address: ***Turbuhaler and Pumpspray, Forskargatan 18, Södertälje, 151 85, Sweden***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***6.2.1-2019-064369*** in accordance with Art. 40 of Directive 2001/83/EC .

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

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-10-11*** , 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 of GMP for active substances [3] referred to in Article 47 of Directive 2001/83/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 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.*

LÄKEMEDELSVERKET · SWEDISH MEDICAL PRODUCTS AGENCY ·

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) 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use 1.2.1.17 Other: multidose powder inhaler(en)
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packing 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)
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Manufacture of active substance. Names of substances subject to inspection :
BUDESONIDE, MICRONISED(en)
FORMOTEROL FUMARATE DIHYDRATE(en)
GLYCOPYRRONIUM BROMIDE(en)
TERBUTALINE SULFATE(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES	
Active Substance : BUDESONIDE, MICRONISED	
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Micronisation and conditioning
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
Active Substance : FORMOTEROL FUMARATE DIHYDRATE	
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Micronisation and conditioning

LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
Active Substance : GLYCOPYRRONIUM BROMIDE	
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Micronisation and conditioning
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
Active Substance : TERBUTALINE SULFATE	
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Micronisation and conditioning
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Clarifying remarks (for public users)

Manufacturing covers hormones or substances with hormonal activity.(Tillverkning inkluderar hormoner eller substanser med hormonell aktivitet). Manufacturing also includes preparation and spraydrying of non-active substances as porous particles.(Tillverkning inkluderar även preparering och spraytorkning av icke-aktiva substanser i form av porösa partiklar.) QC analysis is performed at Forskargatan 18 and Gärtunavägen, Södertälje. (Analys utförs på Forskargatan 18 och Gärtunavägen, Södertälje.)

2019-12-18

LÄKEMEDELSVERKET · SWEDISH MEDICAL PRODUCTS AGENCY

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

Bengt Berglund

Mr. Bengt Berglund
Medical Products Agency
Tel: *+46 18 174600*
Fax: *+46 18 548566*