

Issued by:

Zebulon Manufacturing Plant
1011 N. Arendell Ave
Zebulon, North Carolina
27597

USA

Tel: 919 269 5000, Fax: 919 269 1056



GlaxoSmithKline

Certificate of Analysis

Certificate Date	Certificate Number
3-Mar-20	Manually Generated
Purchase order item/date	
Not Applicable	
Delivery item/date	
Not Applicable	
Order item/date	
Not Applicable	
Customer number	Page
Not Applicable	1 of 3

Product:	ANORO ELLIPTA 55MCG/22MCG 30D CL
Product Code:	60000000010982
Batch Number	GA7Y
Date of Expiry	01 2022
	Date of Manufacture
	01 2020

Description	Specification	Results
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Identification (Filled Strip) Umeclidinium (UV)(ATM02319)	The spectrum of the sample is concordant with that of the umeclidinium bromide reference material.	Complies
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Vilanterol (HPLC with UV detection) (ATM02314)	The retention times of the principal peaks in the sample chromatogram correspond to that of the principal peaks in the vilanterol trifenate reference material chromatogram.	Complies
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Content per Blister by HPLC(mcg/blister) (Filled Strip)

Mean of nominal blister content		
Umeclidinium (ATM02320)	59.4 – 65.6	62.6
Vilanterol (ATM02314)	23.8 – 26.3	24.5

Microbiological Quality of Umeclidinium (Filled Strip) (ATM02335)**Microbial Limit Test**

Total Aerobic Microbial Count	Not Greater Than 10 ² cfu/g	0
Total Yeast and Mold Count	Not Greater Than 10 ¹ cfu/g	0

Absence of specific organisms:

<i>Bile-tolerant Gram negative bacteria</i>	Absent in 1g	Absent in 1g
<i>Pseudomonas aeruginosa</i>	Absent in 1g	Absent in 1g
<i>Staphylococcus aureus</i>	Absent in 1g	Absent in 1g

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Product: ANORO ELLIPTA 55MCG/22MCG 30D CL**Product Code:** 60000000010982**Batch Number** GA7Y**Date of Expiry** 01 2022**Date of Manufacture**

01 2020

Description	Specification	Results
Microbiological Quality of Vilanterol (Filled Strip) (ATM02305)		
Microbial Limit Test		
Total Aerobic Microbial Count	Not Greater Than 10^2 cfu/g	0
Total Yeast and Mold Count	Not Greater Than 10^1 cfu/g	0
Absence of specific organisms:		
<i>Bile-tolerant Gram negative bacteria</i>	Absent in 1g	Absent in 1g
<i>Pseudomonas aeruginosa</i>	Absent in 1g	Absent in 1g
<i>Staphylococcus aureus</i>	Absent in 1g	Absent in 1g
Blister Content Uniformity (Filled Strip)		
Umeclidinium (ATM02320)	Target 62.5mcg	
Vilanterol (ATM02314)	Target 25mcg	
Individual Blister Content	87.5% coverage with 95% confidence blister contents are within 80 – 120% of nominal blister content	Complies
L	≤ 20	Complies
Description (assembled device) (PRS02181)	A plastic inhaler with a light grey body, a red mouthpiece cover and a dose counter, packed in a foil tray which contains a desiccant packet. The tray is sealed with a peelable lid. The inhaler contains two strips of either 30 or 7 regularly distributed blisters, each containing a white powder.	Complies
Identification of Umeclidinium and Vilanterol by HPLC (with UV and fluorescence detection) (assembled device) (ATM02323 or ATM02324)	The retention times of the principal peaks in the HPLC chromatogram of the sample correspond with the principal peaks in the chromatograms for umeclidinium bromide and vilanterol reference materials.	Complies

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Product Code: 60000000010982
Batch Number: GA7Y
Date of Expiry: 01 2022
Date of Manufacture: 01 2020

Description	Specification	Results
Umeclidinium Content Uniformity of Emitted Dose by HPLC (mcg/inhalation) (assembled device) (ATM02323 or ATM02324)	Target: 55	
Individual dose Emitted	87.5% coverage with 95% confidence with goal posts of 80 – 120% target	101
Mean Emitted Dose Content	47 – 63	56
L	≤ 20	10
Vilanterol Content Uniformity of Emitted Dose by HPLC (mcg/inhalation) (assembled device) (ATM02323 or ATM02324)	Target: 22	
Individual dose Emitted	87.5% coverage with 95% confidence with goal posts of 80 – 120% target	98
Mean Emitted Dose Content	19 – 25	22
L	≤ 20	9
Aerodynamic Particle Size Distribution of Umeclidinium by Next Generation Impaction (mcg/inhalation) (assembled device) (ATM02321 or ATM02322)		
Fine Particle Mass (Sum of Stages 3, 4, and 5)	15-23	18
Aerodynamic Particle Size Distribution of Vilanterol by Next Generation Impaction (mcg/inhalation) (assembled device) (ATM02321 or ATM02322)		
Fine Particle Mass (Sum of Stages 3, 4, and 5)	5-9	7

Signature

Johnice Whitley

SR Batch Record Review Spec.

Date

03 MAR 20

Checked by / Date

JHW

03 Mar 20

Certificate of Manufacture

GlaxoSmithKline

ANORO ELLIPTA 55MCG/22MCG 30D CL

Blend Material Number: 10010000001065

Blend Lot Number: 766D

Quantity Released: 12, 648 grams

Master Document Version Number: Version 07

Blend Material Number: 10010000001064

Blend Lot Number: 758G

Quantity Released: 12, 200 grams

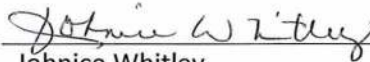
Master Document Version Number: Version 06

1. This is to certify that the documents for the above product were reviewed to ensure conformance to master documents. This product was manufactured and tested in compliance with current Good Manufacturing Practice (cGMP) standards and meets established GlaxoSmithKline specifications.
2. The API used in this batch was manufactured, packaged and tested in accordance with the API GMPs as defined in Annex 18 of the EU GMP Guideline (ICH Q7).
3. The above product has been released for shipment to GlaxoSmithKline Chile.
4. Notifications (unplanned deviations) noted during manufacturing, packaging and testing:

 X No

 Yes, If yes, list Notification Numbers:

(attach copies)



Johnice Whitley

SR Batch Record Review Spec.

02 MAR 20

Date

Checked by / Date

JW

03 Mar 20

GlaxoSmithKline Certificate of Compliance

PRODUCT DESCRIPTION:	ANORO ELLIPTA 55MCG/22MCG 30D CL
MATERIAL NUMBER:	60000000010982
GlaxoSmithKline LOT NUMBER (PACK):	GA7Y
MASTER DOCUMENT VERSION NUMBER (PACK):	Version 04
MASTER DOCUMENT VERSION NUMBER (VI):	Version 02
MASTER DOCUMENT VERSION NUMBER (UMEC):	Version 02
GlaxoSmithKline STRIP LOT NUMBER (VI):	BJ2H
GlaxoSmithKline BLEND LOT NUMBER(VI):	766D
GlaxoSmithKline STRIP LOT NUMBER (UMEC):	B96T
GlaxoSmithKline BLEND LOT NUMBER (UMEC):	758G
PACKAGING EXPIRATION DATE:	01 2022
PACKAGING RELEASED QUANTITY:	18, 000 units

1. This is to certify that the documents for the above lot were reviewed and approved by GlaxoSmithKline Quality Assurance. This lot was packaged in compliance with current Good Manufacturing Practice (cGMP) standards and established GlaxoSmithKline specifications.

2. Notifications (unplanned deviations) noted during packaging:

☒ No

☐ Yes, If yes, list Notification Numbers:

(attach copies)


Johnice Whitley

SR Batch Record Review Spec.

02 MAR 20
Date