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
17-Jan-21	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	XS5X		
Date of Expiry	11 2022	**Date of Manufacture**	11 2020

Description	Specification	Results
Identification (Filled Strip)		
Umeclidinium (UV)(ATM02319)	The spectrum of the sample is concordant with that of the umeclidinium bromide reference material.	Complies
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 trifenatate reference material chromatogram.	Complies
Content per Blister by HPLC(mcg/blister) (Filled Strip)		
Mean of nominal blister content		
Umeclidinium (ATM02320)	59.4 – 65.6	63.8
Vilanterol (ATM02314)	23.8 – 26.3	24.8
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:		
Bile-tolerant Gram negative bacteria	Absent in 1g	Absent in 1g
Pseudomonas aeruginosa	Absent in 1g	Absent in 1g
Staphyloccoccus aureus	Absent in 1g	Absent in 1g

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Product Code: 60000000010982
Batch Number XS5X
Date of Expiry 11 2022 **Date of Manufacture** 11 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:		
Bile-tolerant Gram negative bacteria	Absent in 1g	Absent in 1g
Pseudomonas aeruginosa	Absent in 1g	Absent in 1g
Staphyloccoccus aureus	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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Date of Expiry	11 2022	**Date of Manufacture**	11 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	100
Mean Emitted Dose Content	47 – 63	55
L	≤ 20	9
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	99
Mean Emitted Dose Content	19 – 25	22
L	≤ 20	7
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	19
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
Johnice Whitley
SR Batch Record Review Spec.

Date 17 JAN 21

Checked by / Date
19 Jan 21

GlaxoSmithKline

Certificate of Manufacture

GlaxoSmithKline

ANORO ELLIPTA 55MCG/22MCG 30D CL

Blend Material Number: 10010000002766

Blend Lot Number: GT6F
Quantity Released: 32, 601 grams

Master Document Version Number: Version 08

Blend Material Number: 10010000002033
Blend Lot Number: JH7B
Quantity Released: 32, 210 grams

Master Document Version Number: Version 09

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.

17 JAN 21
Date

1011 N. Arendell Avenue, PO Box 1217, Zebulon, North Carolina 27597
(919) 269-5000
www.gsk.com

Checked by / Date
19 Jan 21

GlaxoSmithKline

GlaxoSmithKline

Certificate of Compliance

PRODUCT DESCRIPTION:	ANORO ELLIPTA 55MCG/22MCG 30D CL
MATERIAL NUMBER:	60000000010982
GlaxoSmithKline LOT NUMBER (PACK):	XS5X
GlaxoSmithKline LOT NUMBER (DEVICE):	S48M
MASTER DOCUMENT VERSION NUMBER (PACK):	Version 07
MASTER DOCUMENT VERSION NUMBER (DEVICE):	Version 09
MASTER DOCUMENT VERSION NUMBER (VI):	Version 07
MASTER DOCUMENT VERSION NUMBER (UMEC):	Version 06
GlaxoSmithKline STRIP LOT NUMBER (VI):	MV9D
GlaxoSmithKline BLEND LOT NUMBER(VI):	GT6F
GlaxoSmithKline STRIP LOT NUMBER (UMEC):	P45L
GlaxoSmithKline BLEND LOT NUMBER (UMEC):	JH7B
PACKAGING EXPIRATION DATE:	11 2022
PACKAGING RELEASED QUANTITY:	14, 395 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:

   X No

   _____ Yes, If yes, list Notification Numbers: _____

   _____

   _____

   (attach copies)

Johnice Whitley — 17 JAN 21

Johnice Whitley
SR Batch Record Review Spec.

Date

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