Issued by:

GlaxoSmithKline
Priory Street
Ware
Hertfordshire
SG12 0DJ
United Kingdom

Tel: +44 (0)1920 463993

Batch Certificate

Certificate Date	Certificate Number
07-MAY-2021	1000366613

Material Description: RELVAR ELLIPTA 92/22MCG 30D_CL
Material Number: 60000000003857
Dosage form: DRY POWDER INHALER **Package size / type:** 1 EACH/CARTON
Strength: 92/22MCG

Regulatory Statement:

Eudra GMDP Certificate Number: UK MIA GMP/IMP 4/15159

Manufacturers Licence Number: MIA4

*Tier 2 testing is only performed if Tier 1 testing is either not carried out or the acceptance criteria was not achieved.

Certification Statement:

I hereby certify that the information provided within this certificate is authentic and accurate.

I hereby certify that all the manufacturing stages of this batch of finished product has been manufactured, including packaging/labelling and Quality Control at the above mentioned site(s) in full compliance with the GMP requirements of the EU and local Regulatory Authority and with the requirements of the Marketing Authorisation of the importing country or product specification file for the Investigational Medicinal Products. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Analysis Results Statement:

The results obtained show compliance with the approved specification

LOT UF4H **EXP** FEB 2023
MANFD FEB 2021

Importing Country:
Chile

Description	Specification	Results
Description	A plastic inhaler with a light grey body, a pale blue 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 30 regularly distributed blisters, each containing a white powder.	Complies
ID of Fluticasone Furoate by UV Spectrophotometry	Concordant with reference	Complies

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Description	Specification	Results
ID of Vilanterol by HPLC (UV detection)	Complies with test	Complies
ID of Fluticasone Furoate by HPLC	Complies with test	Complies
ID of Vilanterol by HPLC	Complies with test	Complies
Mean Fluticasone Furoate Content by HPLC	95 - 105 µg/blister	99
Mean Fluticasone Furoate Content by HPLC (label claim)	95 - 105 %LC	99
Mean Vilanterol Content by HPLC	23.75 - 26.25 µg/blister	24.23
Mean Vilanterol Content by HPLC (label claim)	95 - 105 %LC	97
Fluticasone Furoate Uniformity of Emitted Dose by HPLC	Complies with test	Complies
Vilanterol Uniformity of Emitted Dose by HPLC	Complies with test	Complies
Fine Particle Mass - Fluticasone Furoate (1)	17 - 26 µg/inhalation	22
Fine Particle Mass - Fluticasone Furoate (2)	17 - 26 µg/inhalation	22
Fine Particle Mass - Fluticasone Furoate (3)	17 - 26 µg/inhalation	24
Fine Particle Mass - Fluticasone Furoate (4)	17 - 26 µg/inhalation	21
Fine Particle Mass - Vilanterol (1)	6 - 9 µg/inhalation	7
Fine Particle Mass - Vilanterol (2)	6 - 9 µg/inhalation	7
Fine Particle Mass - Vilanterol (3)	6 - 9 µg/inhalation	8
Fine Particle Mass - Vilanterol (4)	6 - 9 µg/inhalation	7
*Flut.Fur. - Total Aerobic Microbial Count	<=200 cfu/g	0
*Flut.Fur. - Total Yeast and Mould Count	<= 20 cfu/g	0
*Flut.Fur. - Bile- tolerant Gram negative bacteria	Absent in 1 g	Absent
*Flut.Fur. - Pseudomonas aeruginosa	Absent in 1 g	Absent
*Flut.Fur. - Staphylococcus aureus	Absent in 1 g	Absent
*Vilanterol - Total Aerobic Microbial Count	<=200 cfu/g	0
*Vilanterol - Total Yeast and Mould Count	<= 20 cfu/g	0
*Vilanterol - Bile- tolerant Gram negative bacteria	Absent in 1 g	Absent
*Vilanterol - Pseudomonas aeruginosa	Absent in 1 g	Absent
*Vilanterol - Staphylococcus aureus	Absent in 1 g	Absent
Quality Event(s)	If any reportable Quality Event(s) as per Quality Agreement, results will be shown as 'Yes' with Quality Event reference(s). If no reportable Quality Event(s) or if none required as per Quality Agreement, results will be shown as 'Not Required'.	Not Required

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Batch Certificate

Certificate Date	Certificate Number
07-MAY-2021	1000366613

Description	Specification	Results
Release Quantity	Number	18360

Qualified Person.

Approval is provided by Electronic Signature.
The approver's name is shown below.

Richard Temple, 07-MAY-2021 08:45:33

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
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	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:		
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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USA
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GlaxoSmithKline

Certificate of Analysis

Certificate Date: 3-Mar-20
Certificate Number: Manually Generated

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:		
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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Certificate of Analysis

Certificate Date: 3-Mar-20
Certificate Number: Manually Generated

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
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 **Date** 03MAR20

Johnice Whitley
SR Batch Record Review Spec.

Checked by / Date
JW 03Mar 20

GlaxoSmithKline

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 W Whitley

Johnice Whitley
SR Batch Record Review Spec.

02MAR20

Date

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

Checked by / Date
JRW
03 Mar 20

GlaxoSmithKline

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:
   X No
   _____ Yes, If yes, list Notification Numbers: _____
   _____
   _____
   (attach copies)

Johnice W Whitley — 02MAR20

Johnice Whitley — Date
SR Batch Record Review Spec.

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

Checked by / Date
JRW
03 Mar 20