Issued by:

GlaxoSmithKline
Priory Street
Ware
Hertfordshire
SG12 0DJ
United Kingdom

Tel: +44 (0)1920 463993

Batch Certificate

Certificate Date	Certificate Number
11-MAY-2021	1000367046
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Material Description: RELVAR ELLIPTA 184/22MCG 30D_CL
Material Number: 60000000003856
Dosage form: DRY POWDER INHALER **Package size / type:** 1 EACH/CARTON
Strength: 184/22 MCG

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 UP2D **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	190 - 210 µg/blister	196
Mean Fluticasone Furoate Content by HPLC (label claim)	95 - 105 %LC	98
Mean Vilanterol Content by HPLC	23.75 - 26.25 µg/blister	24.47
Mean Vilanterol Content by HPLC (label claim)	95 - 105 %LC	98
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)	33 - 52 µg/inhalation	43
Fine Particle Mass - Fluticasone Furoate (2)	33 - 52 µg/inhalation	39
Fine Particle Mass - Fluticasone Furoate (3)	33 - 52 µg/inhalation	41
Fine Particle Mass - Fluticasone Furoate (4)	33 - 52 µg/inhalation	40
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	8
*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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Description	Specification	Results
Release Quantity	Number	6120

Qualified Person.

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

Sarah Gardiner, 11-MAY-2021 09:40:43