Issued by:
GlaxoSmithKline
Priory Street
Ware
Hertfordshire
SG12 0DJ
United Kingdom

Tel: +44 (0)1920 463993

Batch Certificate

Certificate Date: 04-Jun-2020
Certificate Number: WAR_40000588666

Material Description	RELVAR ELLIPTA 184/22MCG 30D_CL		
Material Number	60000000003856	**Strength**	184/22 MCG
Package Size / Type	1 EACH/CARTON	**Dosage Form**	Dry Powder Inhaler

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.

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.

Analysis Results Statement:

The results obtained show compliance with the approved specification

Lot/Batch	B67C		
Date of Manufacture	FEB 2020	**Date of Expiry**	FEB 2022
Importing Country:	Chile		

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Test	Specification	Result
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
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	202
Mean Fluticasone Furoate Content by HPLC (label claim)	95 - 105 %LC	101
Mean Vilanterol Content by HPLC	23.75 – 26.25 µg/blister	24.48
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	44
Fine Particle Mass - Fluticasone Furoate (2)	33 - 52 µg/inhalation	44
Fine Particle Mass - Fluticasone Furoate (3)	33 - 52 µg/inhalation	43
Fine Particle Mass - Fluticasone Furoate (4)	33 - 52 µg/inhalation	43
Fine Particle Mass - Vilanterol (1)	6 - 9 µg/inhalation	7
Fine Particle Mass - Vilanterol (2)	6 - 9 µg/inhalation	8
Fine Particle Mass - Vilanterol (3)	6 - 9 µg/inhalation	7
Fine Particle Mass - Vilanterol (4)	6 - 9 µg/inhalation	7
Microbiological Quality - Fluticasone Furoate:		

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Water activity using NIR – Tier 1	<=0.6 aw	Not performed
*Microbial Limit Test – Tier 2		
Total Aerobic Microbial Count	<=200 cfu/g	0
Total Yeast and Mould Count	<=20 cfu/g	0
Bile- tolerant Gram negative bacteria	Absent in 1 g	Absent
Pseudomonas aeruginosa	Absent in 1 g	Absent
Staphylococcus aureus	Absent in 1 g	Absent
Microbiological Quality - Vilanterol:		
Water activity using NIR – Tier 1	<=0.6 aw	Not performed
*Microbial Limit Test – Tier 2		
Total Aerobic Microbial Count	<=200 cfu/g	0
Total Yeast and Mould Count	<=20 cfu/g	0
Bile- tolerant Gram negative bacteria	Absent in 1 g	Absent
Pseudomonas aeruginosa	Absent in 1 g	Absent
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.
Release Quantity	Number	13008

Signature R. Temple **Date** 04-JUN-2020

Name R. Temple

Position Qualified Person
Site Ware

Prepared by: _____ Checked by: _____