

**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

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|                             |                                 |                    |                    |
|-----------------------------|---------------------------------|--------------------|--------------------|
| <b>Material Description</b> | RELVAR ELLIPTA 184/22MCG 30D_CL |                    |                    |
| <b>Material Number</b>      | 60000000003856                  | <b>Strength</b>    | 184/22 MCG         |
| <b>Package Size / Type</b>  | 1 EACH/CARTON                   | <b>Dosage Form</b> | 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

|                            |          |                       |          |
|----------------------------|----------|-----------------------|----------|
| <b>Lot/Batch</b>           | B67C     |                       |          |
| <b>Date of Manufacture</b> | FEB 2020 | <b>Date of Expiry</b> | FEB 2022 |
| <b>Importing Country:</b>  | 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).<br><br>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  
Site

Qualified Person  
Ware

Prepared by:

*[Signature]*

Checked by:

*[Signature]*