

# Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 4 Insp GMP 4/117769-0022

## CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER(1),(2)

### Part 1

Issued following an inspection in accordance with :  
Regulation 331A of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following :

The Manufacturer : GLAXOSMITHKLINE

Site address : GLAXOSMITHKLINE, COBDEN STREET, MONTROSE, DD10 8EA, UNITED KINGDOM

Is an active substance manufacturer that has been inspected in accordance with Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 31/08/2022 , it is considered that it complies with

- The principles of GMP for active substances referred to in Regulation B17 and C17 of the Human Medicines Regulations 2012 (SI 2012/1916)

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in MHRA-GMDP. If it does not appear, please contact the issuing authority.

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- (1) *Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
  - (2) *These requirements fulfil the GMP recommendations of WHO.*

### Part 2

#### Human Medicinal Products

Manufacture of active substance. Names of substances subject to inspection :

- [1000007791] DUTASTERIDE
- [4000013535] VILANTEROL TRIFENATATE
- [2000007742] SALBUTAMOL SULPHATE
- [1000007375] LACIDIPINE
- [2000005612] ABACAVIR SULPHATE
- [4000014045] UMECLIDINIUM BROMIDE
- [2000008220] FLUTICASONE PROPIONATE

- [2000008358] BETAMETHASONE VALERATE
- [1000009498] LAMOTRIGINE
- [1000000992] ZANAMIVIR
- [2000008014] CLOBETASOL PROPIONATE
- [2000014516] FLUTICASONE FUROATE

### 3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

#### DUTASTERIDE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
  - 3.1.1 Manufacture Of Active Substance Intermediates
  - 3.1.2 Manufacture Of Crude Active Substance
  - 3.1.3 Salt Formation/Purification steps (eg. Crystallisation)  
Crystallisation
- 3.5 General Finishing Steps
  - 3.5.1 Physical Processing Steps  
Drying
  - 3.5.2 Primary Packaging
  - 3.5.3 Secondary Packaging
- 3.6 Quality Control Testing
  - 3.6.1 Physical / Chemical testing

#### VILANTEROL TRIFENATATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis
  - 3.1.1 Manufacture Of Active Substance Intermediates
  - 3.1.2 Manufacture Of Crude Active Substance
  - 3.1.3 Salt Formation/Purification steps (eg. Crystallisation)  
Crystallisation
- 3.5 General Finishing Steps
  - 3.5.1 Physical Processing Steps  
Drying
  - 3.5.2 Primary Packaging
  - 3.5.3 Secondary Packaging
- 3.6 Quality Control Testing
  - 3.6.1 Physical / Chemical testing

#### SALBUTAMOL SULPHATE

- 3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

3.1.3 Salt Formation/Purification steps (eg. Crystallisation)  
Sulphate salt formation and crystallisation

3.5 General Finishing Steps

3.5.1 Physical Processing Steps  
Drying, Sieving.

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

## LACIDIPINE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

3.1.2 Manufacture Of Crude Active Substance

3.1.3 Salt Formation/Purification steps (eg. Crystallisation)  
Crystallisation

3.5 General Finishing Steps

3.5.1 Physical Processing Steps  
Drying, Sieving.

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

## ABACAVIR SULPHATE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

3.1.3 Salt Formation/Purification steps (eg. Crystallisation)  
Crystallisation and salt formation

3.5 General Finishing Steps

3.5.1 Physical Processing Steps  
Drying, Sieving.

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

#### UMECLIDINIUM BROMIDE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

3.1.2 Manufacture Of Crude Active Substance

3.1.3 Salt Formation/Purification steps (eg. Crystallisation)  
Crystallisation

3.5 General Finishing Steps

3.5.1 Physical Processing Steps  
Drying

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

#### FLUTICASONE PROPIONATE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

3.1.2 Manufacture Of Crude Active Substance

3.1.3 Salt Formation/Purification steps (eg. Crystallisation)  
Crystallisation

3.5 General Finishing Steps

3.5.1 Physical Processing Steps  
Drying, Sieving.

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

#### BETAMETHASONE VALERATE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

3.1.2 Manufacture Of Crude Active Substance

3.1.3 Salt Formation/Purification steps (eg. Crystallisation)  
Crystallisation

3.5 General Finishing Steps

3.5.1 Physical Processing Steps  
Drying, micronisation.

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

## LAMOTRIGINE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

3.1.2 Manufacture Of Crude Active Substance

3.1.3 Salt Formation/Purification steps (eg. Crystallisation)  
Crystallisation

3.5 General Finishing Steps

3.5.1 Physical Processing Steps  
Drying

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

## ZANAMIVIR

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

3.1.2 Manufacture Of Crude Active Substance

3.1.3 Salt Formation/Purification steps (eg. Crystallisation)  
Crystallisation

3.5 General Finishing Steps

3.5.1 Physical Processing Steps  
Rehumidification, Blending, Sieving

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

#### CLOBETASOL PROPIONATE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

3.1.2 Manufacture Of Crude Active Substance

3.1.3 Salt Formation/Purification steps (eg. Crystallisation)  
Crystallisation

3.5 General Finishing Steps

3.5.1 Physical Processing Steps  
Drying, Sieving.

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

#### FLUTICASONE FUROATE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

3.1.2 Manufacture Of Crude Active Substance

3.1.3 Salt Formation/Purification steps (eg. Crystallisation)  
Crystallisation

3.5 General Finishing Steps

3.5.1 Physical Processing Steps  
Drying

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

17/01/2023	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential
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