

# Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 29350 Insp GMP 29350/292119-0008

## 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 : STERLING PHARMA SOLUTIONS LIMITED

Site address : STERLING PHARMA SOLUTIONS LIMITED, DUDLEY LANE, DUDLEY, CRAMLINGTON, NE23 7QG, 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 08/07/2025 , 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 :

- [1000000359] DIMETHYL FUMARATE
- [1000000868] ILOPERIDONE
- [1000017736] ARFORMOTEROL
- [1000021010] SELAMECTIN
- [4000002312] LEVALBUTEROL HYDROCHLORIDE
- [1000017498] LUMACAFTOR

- [4000009871] POLIDOCANOL
- [2000008583] TRIENTINE DIHYDROCHLORIDE
- [2000019612] TOCERANIB PHOSPHATE
- [1000003010] ZILEUTON
- [1000000247] METHOXYFLURANE
- [2000007940] CODEINE PHOSPHATE
- [4000006214] REBOXETINE METHANESULPHONATE
- [1000020604] DIROXIMEL FUMARATE
- [4000014956] LEVALBUTEROL TARTRATE
- [2000006388] FERRIC MALTOL
- [1000007171] BUPRENORPHINE
- [4000009067] OCTENIDINE DIHYDROCHLORIDE
- [1000009451] ACRIVASTINE
- [3000018209] TAZEMETOSTAT
- [1000000540] CANNABIDIOL
- [1000010895] SESTAMIBI
- [2000019613] RACTOPAMINE HYDROCHLORIDE
- [4000008591] CERIUM NITRATE
- [1000021013] SISAPRONIL

### 3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

#### DIMETHYL FUMARATE

- 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
- 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
  - 3.6.2 Microbiological testing (excluding sterility testing)

#### ILOPERIDONE

- 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
- 3.6.2 Microbiological testing (excluding sterility testing)

#### ARFORMOTEROL

- 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
- 3.6.2 Microbiological testing (excluding sterility testing)

#### SELAMECTIN

- 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

#### LEVALBUTEROL HYDROCHLORIDE

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

3.6.2 Microbiological testing (excluding sterility testing)

#### LUMACAFTOR

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

3.6.2 Microbiological testing (excluding sterility testing)

#### POLIDOCANOL

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

3.5 General Finishing Steps

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)

#### TRIENTINE DIHYDROCHLORIDE

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

#### TOCERANIB PHOSPHATE

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

## ZILEUTON

- 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

- 3.5 General Finishing Steps
  - 3.5.1 Physical Processing Steps
  - Drying, Milling
  - 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)

## METHOXYFLURANE

- 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, Milling
  - 3.5.2 Primary Packaging

- 3.5.3 Secondary Packaging

- 3.6 Quality Control Testing

### 3.6.1 Physical / Chemical testing

## CODEINE PHOSPHATE

- 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, Milling
  - 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)

## REBOXETINE METHANESULPHONATE

- 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

## DIROXIMEL FUMARATE

- 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, Milling

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)

LEVALBUTEROL TARTRATE

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

3.6.2 Microbiological testing (excluding sterility testing)

FERRIC MALTOL

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
  - 3.6.2 Microbiological testing (excluding sterility testing)

#### BUPRENORPHINE

- 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
- 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

#### OCTENIDINE DIHYDROCHLORIDE

- 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

3.6.2 Microbiological testing (excluding sterility testing)

#### ACRIVASTINE

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, Milling

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

#### TAZEMETOSTAT

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, Milling

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)

#### CANNABIDIOL

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, Milling

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

#### SESTAMIBI

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

3.6.2 Microbiological testing (excluding sterility testing)

#### RACTOPAMINE HYDROCHLORIDE

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)  
Purified via filtration

3.5 General Finishing Steps  
3.5.1 Physical Processing Steps  
Filtration  
3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing  
3.6.1 Physical / Chemical testing

## CERIUM NITRATE

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  
3.6.2 Microbiological testing (excluding sterility testing)

## SISAPRONIL

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

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| 12/09/2025 | Name and signature of the authorised person of the Competent Authority of United Kingdom<br>Confidential<br>Medicines and Healthcare products Regulatory Agency<br>Tel : Confidential |
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