# Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER: UK API 29350 Insp GMP 29350/292119-0006 [V]

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

## Part 1

Issued following an inspection in accordance with:

Regulation 5 of the current Veterinary Medicines Regulations

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 09/06/2021, 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.

- (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

#### **Veterinary Medicinal Products**

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

- [1000000540] CANNABIDIOL
- [1000000359] DIMETHYL FUMARATE
- [2000008583] TRIENTINE DIHYDROCHLORIDE
- [4000009871] POLIDOCANOL
- [1000021010] SELAMECTIN
- [4000009067] OCTENIDINE DIHYDROCHLORIDE

- [4000008591] CERIUM NITRATE
- [2000019613] RACTOPAMINE HYDROCHLORIDE
- [4000014956] LEVALBUTEROL TARTRATE
- [1000000868] ILOPERIDONE
- [1000007171] BUPRENORPHINE
- [1000000247] METHOXYFLURANE
- [1000020604] DIROXIMEL FUMARATE
- [2000007940] CODEINE PHOSPHATE
- [4000002312] LEVALBUTEROL HYDROCHLORIDE
- [2000019612] TOCERANIB PHOSPHATE
- [1000017498] LUMACAFTOR
- [3000018209] TAZEMETOSTAT
- [2000006388] FERRIC MALTOL
- [1000003010] ZILEUTON
- [1000017736] ARFORMOTEROL
- [1000021013] SISAPRONIL
- [1000009451] ACRIVASTINE
- [1000010895] SESTAMIBI
- [4000006214] REBOXETINE METHANESULPHONATE

# 3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES 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

#### 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

	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)
TRIENTINE DIHYDROCHLOR	RIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates
12.	3.1.2 Manufacture Of Crude Active Substance
"VL,	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
POLIDOCANOL	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates
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3.5	General Finishing Steps  3.5.2 Primary Packaging
	3.3.2 I filliary i ackaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
, 14	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)

3.5.1 Physical Processing Steps

Manufacture of Active Substance by Chemical Synthesis 3.1 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 **Quality Control Testing** 3.6 3.6.1 Physical / Chemical testing OCTENIDINE DIHYDROCHLORIDE 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 **Quality Control Testing** 3.6 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing (excluding sterility testing) **CERIUM NITRATE** Manufacture of Active Substance by Chemical Synthesis 3.1 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 HYDROCHLO	PRIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
- 1/1	3.1.1 Manufacture Of Active Substance Intermediates
" VI.	3.1.2 Manufacture Of Crude Active Substance
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	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
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
V. V.	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
12.	3.1.3 Salt Formation/Purification steps (eg. Crystallisation) Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps
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	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
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	3.5.3 Secondary Packaging
3.6	Quality Control Testing

### 3.6.1 Physical / Chemical 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
	3.3.2 Filliary Fackaging
14.	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
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	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)
CODEINE PHOSPHATE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates

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	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
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	3.6.2 Microbiological testing (excluding sterility testing)
LEVALBUTEROL HYDROCHL	ORIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
5.1	3.1.1 Manufacture Of Active Substance Intermediates
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	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
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3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)
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TOCERANIB PHOSPHATE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates
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	3.1.2 Manufacture Of Crude Active Substance
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	3.1.3 Salt Formation/Purification steps (eg. Crystallisation)
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3.1.2 Manufacture Of Crude Active Substance

Crystallisation

General Finishing Steps 3.5 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 **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 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) **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 General Finishing Steps 3.5 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
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	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 Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps
~ W/ '	Drying
	3.5.2 Primary Packaging
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	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility 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
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3.6.2 Microbiological testing (excluding sterility testing) **ARFORMOTEROL** 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

**Quality Control Testing** 

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

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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

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 **Quality Control Testing** 

3.6.1 Physical / Chemical testing

ACRIVASTINE

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
	2.5.2. Secondary 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
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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
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	3.6.2 Microbiological testing (excluding sterility testing)
REBOXETINE METHANESUL	PHONATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates
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	3.1.2 Manufacture Of Crude Active Substance
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation)
VAL	Crystallisation
3.5	General Finishing Steps

3.1.2 Manufacture Of Crude Active Substance

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

08/01/2024 Name and signature of the authorised person of the Competent Authority of United Kingdom

Confidential

Medicines and Healthcare products Regulatory Agency

Tel: Confidential

Certificate Number: UK API 29350 Insp GMP 29350/292119-0006 [V]