

RESTRICTED – COMMERCIAL

Mrs Allison Tippet

GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS

NORTH LONSDALE ROAD

ULVERSTON

LA12 9DR

UNITED KINGDOM

MHRA

151 Buckingham Palace Road

London SW1W 9SZ

United Kingdom

mhra.gov.uk

original in the post
04-AUG-17

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC.

The competent authority of the United Kingdom confirms the following:

The manufacturer	GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS
Site address	NORTH LONSDALE ROAD ULVERSTON LA12 9DR UNITED KINGDOM

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation: The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 22/05/2017, it is considered that it complies with the principles of GMP for active substances

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 only valid when presented with all pages and both parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear please contact the issuing authority.

Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS

1.1 Sterile products

Not Authorised

1.2 Non-sterile products

Not Authorised

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

Not Authorised

1.5 Packaging

Not Authorised

1.6 Quality control testing

Not Authorised

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

Not Authorised

2.2 Batch certification of imported medicinal products

Not Authorised

2.3 Other importation activities

Not Authorised

CEFTAZIDIME PENTAHYDRATE

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
- Not specified

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

- 3.4.1 Aseptically prepared

3.5 General Finishing Steps

- 3.5.1 Physical Processing Steps
Crystallisation, filtration and drying
- 3.5.2 Primary Packaging
- 3.5.3 Secondary Packaging

3.6 Quality Control Testing

- 3.6.1 Physical / Chemical testing
- 3.6.3 Microbiological testing (including sterility testing)

4 Other Activities

Not Authorised

AVIBACTAM SODIUM

3. MANUFACTURING OPERATIONS

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

Special Requirements:

Other highly sensitising antibiotics

3.1.3 Salt Formation/Purification Steps (e.g. Crystallisation)

Crystallisation, drying

Special Requirements:

Other highly sensitising antibiotics

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

3.4.1 Aseptically prepared

Special Requirements:

Other highly sensitising antibiotics

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Drying, milling

Special Requirements:

Other highly sensitising antibiotics

3.5.2 Primary Packaging

Special Requirements:

Other highly sensitising antibiotics

3.5.3 Secondary Packaging

Special Requirements:

Other highly sensitising antibiotics

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

Special Requirements:

Other highly sensitising antibiotics

3.6.3 Microbiological testing (including sterility testing)

Special Requirements:
Other highly sensitising antibiotics

4 Other Activities
Not Authorised

CEFUROXIME AXETIL

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
Not specified

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

- 3.5.1 Physical Processing Steps
Spray drying
- 3.5.2 Primary Packaging
- 3.5.3 Secondary Packaging

3.6 Quality Control Testing

- 3.6.1 Physical / Chemical testing

4 Other Activities

Not Authorised

CEFUROXIME SODIUM

3. MANUFACTURING OPERATIONS

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 (e.g. Crystallisation)
- Not Specified

3.2 **Processing Activities of Active Substance from Natural Sources**

Not Authorised

3.3 **Manufacture of Active Substance using Biological Processes**

Not Authorised

3.4 **Manufacture of sterile active substance**

- 3.4.1 Aseptically prepared
- Special Requirements:

3.5 **General Finishing Steps**

- 3.5.1 Physical Processing Steps
- Crystallisation, filtration and drying
- 3.5.2 Primary Packaging
- 3.5.3 Secondary Packaging

3.6 **Quality Control Testing**

- 3.6.1 Physical / Chemical testing
- 3.6.3 Microbiological testing (including sterility testing)

4 **Other Activities**

Not Authorised

Any restrictions or clarifying remarks related to the scope of this certificate:

N/A

1. Building(s)/Area(s)

This inspection cover Buildings 11 and 14.

2. Room(s)

N/A

3. Line(s) Equipment(s)

N/A

4. QC testing

N/A

5. Medicinal Product(s)/IMP(s)

N/A

**Name of the authorised person of the
Competent Authority of the United Kingdom**

Norman Gray
GMP Inspector
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Date: 07/07/2017