Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 4 Insp GMP 4/15697-0019

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 : GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS

Site address : GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS, NORTH LONSDALE ROAD, ULVERSTON, LA12 9DR, 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 22/05/2017 , 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

Human Medicinal Products

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

- [2000008119] CEFTAZIDIME PENTAHYDRATE
- [2000015677] AVIBACTAM SODIUM
- [2000008117] CEFUROXIME AXETIL
- [2000008116] CEFUROXIME SODIUM

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

CEFTAZIDIME PENTAHYDRATE

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)
	Not specified
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)

AVIBACTAM SODIUM

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates
	Other highly sensitising antibiotics
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation)
	Crystallisation, drying
	Other highly sensitising antibiotics
3.4	Manufacture of sterile active substance
	3.4.1 Aseptically prepared
	Other highly sensitising antibiotics
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps
	Drying, milling
	Other highly sensitising antibiotics
	3.5.2 Primary Packaging
	Other highly sensitising antibiotics
	3.5.3 Secondary Packaging
	Other highly sensitising antibiotics

3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	Other highly sensitising antibiotics
	3.6.3 Microbiological testing (including sterility testing)
	Other highly sensitising antibiotics

CEFUROXIME AXETIL

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)
	Not specified
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

CEFUROXIME SODIUM

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)
	Not Specified
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)

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
This inspection cover Buildings 11 and 14.				

07/07/2017	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential