Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 40128 Insp GMP 40128/4100215-0007

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 : QILU ANTIBIOTICS PHARMACEUTICAL COMPANY LIMITED

Site address : QILU ANTIBIOTICS PHARMACEUTICAL COMPANY LIMITED, 849 DONGJIA TOWN, LICHENG DISTRICT, JINAN CITY, CN-250105, CHINA

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 17/11/2014 , 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 :

- [3000017463] CEFOPERAZONE SODIUM STERILE
- [4000013905] CEFEPIME DIHYDROCHLORIDE MONOHYDRATE STERILE
- [3000000925] L-ARGININE STERILE
- [4000011403] CEFOTAXIME SODIUM STERILE
- [4000013903] CEFAZOLIN SODIUM STERILE
- [4000013904] CEFUROXIME SODIUM STERILE

- [4000008058] CEFTRIAXONE SODIUM STERILE
- [4000008765] CEFTAZIDIME PENTAHYDRATE STERILE
- [2000016869] CEFTAZIDIME PENTAHYDRATE WITH SODIUM CARBONATE FOR INJECTION

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

CEFOPERAZONE SODIUM STERILE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

B-lactam Antibiotics

3.1.2 Manufacture Of Crude Active Substance

B-lactam Antibiotics

3.1.3 Salt Formation/Purification steps (eg. Crystallisation)
Crystallisation, purification, blending
B-lactam Antibiotics

3.4 Manufacture of sterile active substance

3.4.1 Aseptically prepared

B-lactam Antibiotics

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, granulating and mixing
B-lactam Antibiotics

3.5.2 Primary Packaging

B-lactam Antibiotics

3.5.3 Secondary Packaging

B-lactam Antibiotics

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

B-lactam Antibiotics

3.6.3 Microbiological testing (including sterility testing)

B-lactam Antibiotics

CEFEPIME DIHYDROCHLORIDE MONOHYDRATE STERILE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

B-lactam Antibiotics

3.1.2 Manufacture Of Crude Active Substance

B-lactam Antibiotics

	3.1.3 Salt Formation/Purification steps (eg. Crystallisation)
	Crystallisation, purification, blending
	B-lactam Antibiotics
3.4	Manufacture of sterile active substance
	3.4.1 Aseptically prepared
	B-lactam Antibiotics
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps
	Drying, granulating and mixing
	B-lactam Antibiotics
	3.5.2 Primary Packaging
	B-lactam Antibiotics
	3.5.3 Secondary Packaging
	B-lactam Antibiotics
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	B-lactam Antibiotics
	3.6.3 Microbiological testing (including sterility testing)
	B-lactam Antibiotics

L-ARGININE STERILE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates
	B-lactam Antibiotics
	3.1.2 Manufacture Of Crude Active Substance
	B-lactam Antibiotics
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation)
	Crystallisation, filtration, blending
3.4	Manufacture of sterile active substance
	3.4.1 Aseptically prepared
	B-lactam Antibiotics
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps
	Drying, granulating and mixing
	B-lactam Antibiotics
	3.5.2 Primary Packaging
	B-lactam Antibiotics

3.5.3 Secondary Packaging

B-lactam Antibiotics

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

B-lactam Antibiotics

3.6.3 Microbiological testing (including sterility testing)

B-lactam Antibiotics

CEFOTAXIME SODIUM STERILE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

B-lactam Antibiotics

3.1.2 Manufacture Of Crude Active Substance

B-lactam Antibiotics

3.1.3 Salt Formation/Purification steps (eg. Crystallisation)
Crystallisation, purification, blending
B-lactam Antibiotics

3.4 Manufacture of sterile active substance

3.4.1 Aseptically prepared

B-lactam Antibiotics

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Drying, granulating and mixing
B-lactam Antibiotics

3.5.2 Primary Packaging

B-lactam Antibiotics

3.5.3 Secondary Packaging

B-lactam Antibiotics

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

B-lactam Antibiotics

3.6.3 Microbiological testing (including sterility testing)

B-lactam Antibiotics

CEFAZOLIN SODIUM STERILE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

B-lactam Antibiotics

3.1.2 Manufacture Of Crude Active Substance

B-lactam Antibiotics

3.1.3 Salt Formation/Purification steps (eg. Crystallisation)

Lyophilisation, purification, blending

B-lactam Antibiotics

3.4 Manufacture of sterile active substance

3.4.1 Aseptically prepared

B-lactam Antibiotics

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Drying, granulating and mixing

B-lactam Antibiotics

3.5.2 Primary Packaging

B-lactam Antibiotics

3.5.3 Secondary Packaging

B-lactam Antibiotics

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

B-lactam Antibiotics

3.6.3 Microbiological testing (including sterility testing)

B-lactam Antibiotics

CEFUROXIME SODIUM STERILE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

B-lactam Antibiotics

3.1.2 Manufacture Of Crude Active Substance

B-lactam Antibiotics

3.1.3 Salt Formation/Purification steps (eg. Crystallisation)

Crystallisation, purification, blending

B-lactam Antibiotics

3.4 Manufacture of sterile active substance

3.4.1 Aseptically prepared

B-lactam Antibiotics

3.5 General Finishing Steps

	3.5.1 Physical Processing Steps
	Drying, granulating and mixing
	B-lactam Antibiotics
	3.5.2 Primary Packaging
	B-lactam Antibiotics
	3.5.3 Secondary Packaging
	B-lactam Antibiotics
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	B-lactam Antibiotics
	3.6.3 Microbiological testing (including sterility testing)
	B-lactam Antibiotics

CEFTRIAXONE SODIUM STERILE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates
	B-lactam Antibiotics
	3.1.2 Manufacture Of Crude Active Substance
	B-lactam Antibiotics
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation)
	Crystallisation, purification, blending
	B-lactam Antibiotics
3.4	Manufacture of sterile active substance
	3.4.1 Aseptically prepared
	B-lactam Antibiotics
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps
	Drying, granulating and mixing
	B-lactam Antibiotics
	3.5.2 Primary Packaging
	B-lactam Antibiotics
	3.5.3 Secondary Packaging
	B-lactam Antibiotics
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	B-lactam Antibiotics

3.6.3 Microbiological testing (including sterility testing)

B-lactam Antibiotics

CEFTAZIDIME PENTAHYDRATE STERILE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

B-lactam Antibiotics

3.1.2 Manufacture Of Crude Active Substance

B-lactam Antibiotics

3.1.3 Salt Formation/Purification steps (eg. Crystallisation)

Crystallisation, purification, blending

B-lactam Antibiotics

3.4 Manufacture of sterile active substance

3.4.1 Aseptically prepared

B-lactam Antibiotics

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Drying, granulating and mixing

B-lactam Antibiotics

3.5.2 Primary Packaging

B-lactam Antibiotics

3.5.3 Secondary Packaging

B-lactam Antibiotics

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

B-lactam Antibiotics

3.6.3 Microbiological testing (including sterility testing)

B-lactam Antibiotics

CEFTAZIDIME PENTAHYDRATE WITH SODIUM CARBONATE FOR INJECTION

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

B-lactam Antibiotics

3.1.2 Manufacture Of Crude Active Substance

B-lactam Antibiotics

3.1.3 Salt Formation/Purification steps (eg. Crystallisation)

Crystallisation, purification, blending

B-lactam Antibiotics

3.4	Manufacture of sterile active substance
	3.4.1 Aseptically prepared
	B-lactam Antibiotics
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps
	Drying, granulating and mixing
	B-lactam Antibiotics
	3.5.2 Primary Packaging
	B-lactam Antibiotics
	3.5.3 Secondary Packaging
	B-lactam Antibiotics
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	B-lactam Antibiotics
	3.6.3 Microbiological testing (including sterility testing)
	B-lactam Antibiotics

Restrictions or Remarks

Following a risk-based review of GMP compliance information conducted on 9th November 2017, the validity period of this certificate is extended to 9th November 2018.

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
Buildings authorised for EU products are Workshop 500 and Workshop 300/1000				The certifcate covers the production of sterile Cephalosporin materilas only

09/11/2017	Name and signature of the authorised person of the Competent Authority of United Kingdom
	Confidential
	Medicines and Healthcare products Regulatory Agency
	Tel : Confidential