Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 35431 Insp GMP 35431/987642-0001

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 : NORTH CHINA PHARMACEUTICAL GROUP SEMISYNTECH COMPANY LIMITED

Site address : NORTH CHINA PHARMACEUTICAL GROUP SEMISYNTECH COMPANY LIMITED, 20, YANGZI ROAD, SHIJIAZHUANG ECONOMIC AND TECHNOLOGICAL, SHIJIAZHUANG, RC-052165, 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 16/11/2015 , 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 :

- [4000006303] AMOXICILLIN TRIHYDRATE
- [2000008461] AMPICILLIN TRIHYDRATE

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

AMOXICILLIN TRIHYDRATE

3.1 Manufacture of Active Substance by Chemical Synthesis

MHRA-GMDP MHRA

	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
	B-lactam Antibiotics
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps
	DRYING, MILLING BLENDING
	B-lactam Antibiotics
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

AMPICILLIN TRIHYDRATE

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
	B-lactam Antibiotics
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps
	DRYING, MILLING, BLENDING
	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

MHRA-GMDP MHRA-GMDP MHRA MHRA

3.6.2 Microbiological testing (excluding sterility testing)

B-lactam Antibiotics

Restrictions or Remarks

Applies to active substance manufactured in workshop 801 only

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
Applies to active substance manufactured in workshop 801 only				

18/02/2016	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential

MHRA-GMDP