Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 12323 Insp GMP/GDP 6464/2814220-0006

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 : WAYMADE PLC

Site address : WAYMADE PLC, JOSSELIN ROAD, BURNT MILLS INDUSTRIAL ESTATE, BASILDON, SS13 1QF, 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 12/12/2018 , 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 :

- [1000003268] IBANDRONIC ACID
- [1000003309] DOXEPIN
- [1000004171] CLOBAZAM
- [2000007338] HYDROCORTISONE ACETATE
- [3000004591] ESTRIOL
- [1000009701] NAPROXEN

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- [2000006651] CHLORAL BETAINE
- [2000008148] GRANISETRON HYDROCHLORIDE
- [1000004182] CLIOQUINOL
- [2000007602] ERYTHROMYCIN STEARATE
- [4000014974] POTASSIUM CLAVULANATE - AVICEL BLEND (1:1)
- [1000009500] BENZYL BENZOATE
- [2000007339] HYDRALAZINE HYDROCHLORIDE
- [1000000089] METHYLDOPA
- [2000007430] AURANOFIN

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

IBANDRONIC ACID

3.2	Processing Activities of Active Substance from Natural Sources
	3.2.7 Other
	r23r
	B-lactam Antibiotics
	Other highly sensitising antibiotics
	Live Cells
	Pathogenic Organisms (Biosafety Level 3 or 4)
	Radiopharmaceuticals
	Ectoparasiticides
	Other : r23r32

DOXEPIN

3.2	Processing Activities of Active Substance from Natural Sources
	3.2.1 Plant Source Extraction
	B-lactam Antibiotics
	Other highly sensitising antibiotics
	Live Cells
	Pathogenic Organisms (Biosafety Level 3 or 4)
	Radiopharmaceuticals
	Ectoparasiticides
	Other : rfe

CLOBAZAM

3.3	Manufacture of Active Substance using Biological Processes
	3.3.3 Isolation / Purification
	B-lactam Antibiotics
	Other highly sensitising antibiotics
	Live Cells
	Pathogenic Organisms (Biosafety Level 3 or 4)
	Radiopharmaceuticals
	Ectoparasiticides
	Other : 4234

HYDROCORTISONE ACETATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates

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3.4 Manufacture of sterile active substance

3.4.1 Aseptically prepared

B-lactam Antibiotics
Other highly sensitising antibiotics
Live Cells
Pathogenic Organisms (Biosafety Level 3 or 4)
Radiopharmaceuticals
Ectoparasiticides
Other : 423

3.4.2 Terminally sterilised

B-lactam Antibiotics
Other highly sensitising antibiotics
Live Cells
Pathogenic Organisms (Biosafety Level 3 or 4)
Radiopharmaceuticals
Ectoparasiticides
Other : 4234

ESTRIOL

3.2 Processing Activities of Active Substance from Natural Sources

3.2.3 Human Source Extraction

B-lactam Antibiotics
Other highly sensitising antibiotics
Live Cells
Pathogenic Organisms (Biosafety Level 3 or 4)
Radiopharmaceuticals
Ectoparasiticides
Other : r34r34

3.2.5 Modification of extracted substance

B-lactam Antibiotics
Other highly sensitising antibiotics
Live Cells
Pathogenic Organisms (Biosafety Level 3 or 4)
Radiopharmaceuticals
Ectoparasiticides
Other : r34r34

3.2.6 Purification of extracted substance

B-lactam Antibiotics
Other highly sensitising antibiotics
Live Cells
Pathogenic Organisms (Biosafety Level 3 or 4)
Radiopharmaceuticals
Ectoparasiticides
Other : r34r34

MHRA-GMDP MHRA

NAPROXEN

3.3	Manufacture of Active Substance using Biological Processes
	3.3.2 Cell Culture
	42342
	B-lactam Antibiotics
	Other highly sensitising antibiotics
	Live Cells
	Pathogenic Organisms (Biosafety Level 3 or 4)
	Radiopharmaceuticals
	Ectoparasiticides
	Other : 4234

CHLORAL BETAINE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation)
	freferf
	B-lactam Antibiotics
	Other highly sensitising antibiotics
	Live Cells
	Pathogenic Organisms (Biosafety Level 3 or 4)
	Radiopharmaceuticals
	Ectoparasiticides
	Other : fewfew

GRANISETRON HYDROCHLORIDE

3.3	Manufacture of Active Substance using Biological Processes
	3.3.5 Other
	432432
	B-lactam Antibiotics
	Other highly sensitising antibiotics
	Live Cells
	Pathogenic Organisms (Biosafety Level 3 or 4)
	Radiopharmaceuticals
	Ectoparasiticides
	Other : 423

CLIOQUINOL

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.4 Other
	r32r23r2
	B-lactam Antibiotics
	Other highly sensitising antibiotics
	Live Cells
	Pathogenic Organisms (Biosafety Level 3 or 4)
	Radiopharmaceuticals
	Ectoparasiticides
	Other : r32r32

ERYTHROMYCIN STEARATE

3.2	Processing Activities of Active Substance from Natural Sources

MHRA-GMDP MHRA-GMDP MHRA MHRA

3.2.2 Animal Source Extraction

B-lactam Antibiotics
Other highly sensitising antibiotics
Live Cells
Pathogenic Organisms (Biosafety Level 3 or 4)
Radiopharmaceuticals
Ectoparasiticides
Other : fef

3.2.5 Modification of extracted substance

B-lactam Antibiotics
Other highly sensitising antibiotics
Live Cells
Pathogenic Organisms (Biosafety Level 3 or 4)
Radiopharmaceuticals
Ectoparasiticides
Other : fef

3.2.6 Purification of extracted substance

B-lactam Antibiotics
Other highly sensitising antibiotics
Live Cells
Pathogenic Organisms (Biosafety Level 3 or 4)
Radiopharmaceuticals
Ectoparasiticides
Other : fef

POTASSIUM CLAVULANATE - AVICEL BLEND (1:1)

3.3 Manufacture of Active Substance using Biological Processes

3.3.4 Modification

B-lactam Antibiotics
Other highly sensitising antibiotics
Live Cells
Pathogenic Organisms (Biosafety Level 3 or 4)
Radiopharmaceuticals
Ectoparasiticides
Other : 423423

BENZYL BENZOATE

3.1 Manufacture of Active Substance by Chemical Synthesis

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3.1.2 Manufacture Of Crude Active Substance

B-lactam Antibiotics
Other highly sensitising antibiotics
Live Cells
Pathogenic Organisms (Biosafety Level 3 or 4)
Radiopharmaceuticals
Ectoparasiticides
Other : fwefew

3.3 Manufacture of Active Substance using Biological Processes

3.3.1 Fermentation

HYDRALAZINE HYDROCHLORIDE

3.2 Processing Activities of Active Substance from Natural Sources

3.2.4 Mineral Source Extraction

B-lactam Antibiotics
Other highly sensitising antibiotics
Live Cells
Pathogenic Organisms (Biosafety Level 3 or 4)
Radiopharmaceuticals
Ectoparasiticides
Other : e23e

3.2.5 Modification of extracted substance

B-lactam Antibiotics
Other highly sensitising antibiotics
Live Cells
Pathogenic Organisms (Biosafety Level 3 or 4)
Radiopharmaceuticals
Ectoparasiticides
Other : e23e

3.2.6 Purification of extracted substance

B-lactam Antibiotics
Other highly sensitising antibiotics
Live Cells
Pathogenic Organisms (Biosafety Level 3 or 4)
Radiopharmaceuticals
Ectoparasiticides
Other : e23e

METHYLDOPA

3.3 Manufacture of Active Substance using Biological Processes

MHRA-GMDP

3.3.1 Fermentation

B-lactam Antibiotics
Other highly sensitising antibiotics
Live Cells
Pathogenic Organisms (Biosafety Level 3 or 4)
Radiopharmaceuticals
Ectoparasiticides
Other : 423423

AURANOFIN

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

B-lactam Antibiotics
Other highly sensitising antibiotics
Live Cells
Pathogenic Organisms (Biosafety Level 3 or 4)
Radiopharmaceuticals
Ectoparasiticides
Other : 5tr4

3.4 Manufacture of sterile active substance

3.4.1 Aseptically prepared

B-lactam Antibiotics
Other highly sensitising antibiotics
Live Cells
Pathogenic Organisms (Biosafety Level 3 or 4)
Radiopharmaceuticals
Ectoparasiticides
Other : 54t54t

3.4.2 Terminally sterilised

B-lactam Antibiotics
Other highly sensitising antibiotics
Live Cells
Pathogenic Organisms (Biosafety Level 3 or 4)
Radiopharmaceuticals
Ectoparasiticides
Other : t54t45

3.5 General Finishing Steps

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3.5.1 Physical Processing Steps

t54gt54g

B-lactam Antibiotics

Other highly sensitising antibiotics

Live Cells

Pathogenic Organisms (Biosafety Level 3 or 4)

Radiopharmaceuticals

Ectoparasiticides

Other : 45t4

3.5.2 Primary Packaging

B-lactam Antibiotics

Other highly sensitising antibiotics

Live Cells

Pathogenic Organisms (Biosafety Level 3 or 4)

Radiopharmaceuticals

Ectoparasiticides

Other : t45t4

3.5.3 Secondary Packaging

B-lactam Antibiotics

Other highly sensitising antibiotics

Live Cells

Pathogenic Organisms (Biosafety Level 3 or 4)

Radiopharmaceuticals

Ectoparasiticides

Other : 45t45

3.5.4 Other

g54g54

B-lactam Antibiotics

Other highly sensitising antibiotics

Live Cells

Pathogenic Organisms (Biosafety Level 3 or 4)

Radiopharmaceuticals

Ectoparasiticides

Other : 45t45t

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

B-lactam Antibiotics

Other highly sensitising antibiotics

Live Cells

Pathogenic Organisms (Biosafety Level 3 or 4)

Radiopharmaceuticals

Ectoparasiticides

Other : 645645

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3.6.2 Microbiological testing (excluding sterility testing)

B-lactam Antibiotics
Other highly sensitising antibiotics
Live Cells
Pathogenic Organisms (Biosafety Level 3 or 4)
Radiopharmaceuticals
Ectoparasiticides
Other : 4646

3.6.3 Microbiological testing (including sterility testing)

B-lactam Antibiotics
Other highly sensitising antibiotics
Live Cells
Pathogenic Organisms (Biosafety Level 3 or 4)
Radiopharmaceuticals
Ectoparasiticides
Other : t54t45

3.6.4 Biological Testing

B-lactam Antibiotics
Other highly sensitising antibiotics
Live Cells
Pathogenic Organisms (Biosafety Level 3 or 4)
Radiopharmaceuticals
Ectoparasiticides
Other : t54t45

Restrictions or Remarks

Hello

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
Building	Room2	None	None	None

15/04/2019	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential

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