Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 29595 Insp GMP/GDP 29595/18244-0042

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 : PIRAMAL HEALTHCARE UK LIMITED

Site address : PIRAMAL HEALTHCARE UK LIMITED , WHALTON ROAD, MORPETH, NE61 3YA, 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 15/06/2021 , 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 :

- [4000014458] MISOPROSTOL:HYPROMELLOSE 1:100 DISPERSION
- [1000009436] SPIRONOLACTONE
- [1000018194] FOSTEMSAVIR
- [1000009076] MISOPROSTOL
- [4000007373] CANRENOATE POTASSIUM
- [1000008761] HYDROFLUMETHIAZIDE
- [4000014629] FERRIC TRIMALTOL

- [1000001486] HALOPERIDOL
- [2000005830] PARECOXIB SODIUM

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

MISOPROSTOL:HYPROMELLOSE 1:100 DISPERSION

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) .HPLC column purification (of misoprostol)
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps .Dispersing of Misoprostol pure with Hypromellose, milling.
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)

SPIRONOLACTONE

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
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)

FOSTEMSAVIR

3.1	Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

Other : Fostemsavir is not a B-Lactam Antibiotic, however degradation products containing a B-Lactam ring st

3.1.2 Manufacture Of Crude Active Substance

Other : Fostemsavir is not a B-Lactam Antibiotic, however degradation products containing a B-Lactam ring st

3.1.3 Salt Formation/Purification steps (eg. Crystallisation)

Crystallisation

Other : Fostemsavir is not a B-Lactam Antibiotic, however degradation products containing a B-Lactam ring st

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Milling

Other : Fostemsavir is not a B-Lactam Antibiotic, however degradation products containing a B-Lactam ring st

3.5.2 Primary Packaging

Other : Fostemsavir is not a B-Lactam Antibiotic, however degradation products containing a B-Lactam ring st

3.5.3 Secondary Packaging

Other : Fostemsavir is not a B-Lactam Antibiotic, however degradation products containing a B-Lactam ring st

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

Other : Fostemsavir is not a B-Lactam Antibiotic, however degradation products containing a B-Lactam ring st

MISOPROSTOL

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)

.HPLC column purification

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

	3.6.2 Microbiological testing (excluding sterility testing)

CANRENOATE POTASSIUM

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) .Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps .Drying
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)

HYDROFLUMETHIAZIDE

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) Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Drying
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)

FERRIC TRIMALTOL

3.1	Manufacture of Active Substance by Chemical Synthesis

	3.1.1 Manufacture Of Active Substance Intermediates
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Milled
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)

HALOPERIDOL

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) Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps .Drying
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)

PARECOXIB 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) Salt formation and optional recrystallisation
3.5	General Finishing Steps

3.5.1 Physical Processing Steps

Drying, sieving

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

16/09/2021	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential