Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 29595 Insp GMP 29595/18244-0047 [H]

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 23/12/2024 , 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 :

- [1000018194] FOSTEMSAVIR
- [4000007373] CANRENOATE POTASSIUM
- [2000005830] PARECOXIB SODIUM
- [1000009076] MISOPROSTOL
- [4000014458] MISOPROSTOL:HYPROMELLOSE 1:100 DISPERSION
- [1000009436] SPIRONOLACTONE

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

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 structure have the potential to form in the solid state in the presence of light during manufacture and storage of the final intermediate, Phosphoester and the API Fostemsavir. Facility and manufacturing controls have been designed to mitigate the risk of potential formation and cross-contamination of photo-degradation products containing a B-Lactam ring.

3.1.2 Manufacture Of Crude Active Substance

Other : Fostemsavir is not a B-Lactam Antibiotic, however degradation products containing a B-Lactam ring structure have the potential to form in the solid state in the presence of light during manufacture and storage of the final intermediate, Phosphoester and the API Fostemsavir. Facility and manufacturing controls have been designed to mitigate the risk of potential formation and cross-contamination of photo-degradation products containing a B-Lactam ring.

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 structure have the potential to form in the solid state in the presence of light during manufacture and storage of the final intermediate, Phosphoester and the API Fostemsavir. Facility and manufacturing controls have been designed to mitigate the risk of potential formation and cross-contamination of photo-degradation products containing a B-Lactam ring.

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 structure have the potential to form in the solid state in the presence of light during manufacture and storage of the final intermediate, Phosphoester and the API Fostemsavir. Facility and manufacturing controls have been designed to mitigate the risk of potential formation and cross-contamination of photo-degradation products containing a B-Lactam ring.

3.5.2 Primary Packaging

Other : Fostemsavir is not a B-Lactam Antibiotic, however degradation products containing a B-Lactam ring structure have the potential to form in the solid state in the presence of light during manufacture and storage of the final intermediate, Phosphoester and the API Fostemsavir. Facility, manufacturing controls and packaging have been designed to mitigate the risk of potential formation and cross-contamination of photo-degradation products containing a B-Lactam ring.

3.5.3 Secondary Packaging

Other : Fostemsavir is not a B-Lactam Antibiotic, however degradation products containing a B-Lactam ring structure have the potential to form in the solid state in the presence of light during manufacture and storage of the final intermediate, Phosphoester and the API Fostemsavir. Facility, manufacturing controls and packaging have been designed to mitigate the risk of potential formation and cross-contamination of photo-degradation products containing a B-Lactam ring.

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 structure have the potential to form in the solid state in the presence of light during manufacture and storage of the final intermediate, Phosphoester and the API Fostemsavir. Facility, manufacturing controls, packaging and QC testing facilities have been designed to mitigate the risk of potential formation and cross-contamination of photo-degradation products containing a B-Lactam ring.

CANRENOATE POTASSIUM

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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)

MISOPROSTOL

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

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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)

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

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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)

Restrictions or Remarks

This certificate is issued based on a desk-based assessment of GMP compliance information provided by the manufacturer. This certificate should be us
ed in combination with the relevant authorisation/registration. A risk-based site inspection programme remains in force.

17/04/2026	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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