Medicines and Healthcare products Regulatory Agency

REGISTRATION OF MANUFACTURER, IMPORTER OR DISTRIBUTOR OF ACTIVE SUBSTANCES TO BE USED AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

	Registrant Details
1. Registration Number	UK API 29595
2. Name or corporate name of registrant	PIRAMAL HEALTHCARE UK LIMITED
3. Permanent or legal address of registrant	PIRAMAL HEALTHCARE UK LIMITED, WHALTON ROAD, MORPETH, NORTHUMBERLAND, NE61 3YA, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	PIRAMAL HEALTHCARE UK LIMITED , WHALTON ROAD, MORPETH, NORTHUMBERLAND, NE61 3YA, UNITED KINGDOM PIRAMAL HEALTHCARE UK LIMITED, EARLS ROAD, GRANGEMOUTH, FK3 8XG, UNITED KINGDOM
5. National legal basis of registration	Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916)
6. Name of responsible officer of the competent authority of the member state validating the registration	Confidential
7. Date	27/04/2026

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in MHRA-GMDP.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

SCOPE OF REGISTRATION

Name and address of the site

PIRAMAL HEALTHCARE UK LIMITED , WHALTON ROAD, MORPETH, NORTHUMBERLAND, NE61 3YA, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance
FOSTEMSAVIR
1000018194

A	Manufacture of Active Substance by Chemical Synthesis

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	A.1 Manufacture of Active Substance Intermediates **Special Requirements** 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.
	A.2 Manufacture of Crude Active Substance **Special Requirements** 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.
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation **Special Requirements** 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.
E	General Finishing Steps
	E.1 Physical Processing Steps Milling **Special Requirements** 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.
	E.2 Primary Packaging **Special Requirements** 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.

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	E.3 Secondary Packaging **Special Requirements** 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.
F	Quality Control Testing
	F.1 Physical / Chemical testing **Special Requirements** 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.

Active substance
PARECOXIB SODIUM
2000005830

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Salt formation and optional recrystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, sieving
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance
MISOPROSTOL
1000009076

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates

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	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) .HPLC column purification
E	General Finishing Steps
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

CANRENOATE POTASSIUM

4000007373

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) .Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps .Drying
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

MISOPROSTOL:HYPROMELLOSE 1:100 DISPERSION

4000014458

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance

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	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) .HPLC column purification (of misoprostol)
E	General Finishing Steps
	E.1 Physical Processing Steps .Dispersing of Misoprostol pure with Hypromellose, milling.
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance
SPIRONOLACTONE
1000009436

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
E	General Finishing Steps
	E.1 Physical Processing Steps Micronisation
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
TETRACYCLINE HYDROCHLORIDE (2000007377)	**NINGXIA QIYUAN PHARMACEUTICAL COMPANY LIMITED**, NO 1 QIYUAN STEET, WANGYUAN INDUSTRIAL AREA, YINCHUAN, NINGXIA, CN-750101, CHINA	

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	CORDEN PHARMA COLORADO INC., 2075 NORTH 55TH STREET, BOULDER, 80301, UNITED STATES
BEMPEDOIC ACID (1000017714)	**NEULAND LABORATORIES LIMITED**, UNIT 2, PLOT NO. 92-94 AND 257-259, IDA, PASHAMYLARAM, PASHAMYLARAM VILLAGE, PATANCHERU MANDAL, SANGAREDDY, TELANGANA, IN-502319, INDIA
OBETICHOLIC ACID (1000018845)	**PHARMACIA AND UPJOHN COMPANY LLC**, 7000 PORTAGE ROAD, KALAMAZOO, 49001, UNITED STATES
BENZBROMARONE (1000003448)	**IPCA LABORATORIES LIMITED**, PLOT NOS. 4722, 4723, 4731 AND 4732, GIDC ESTATE, ANKLESHWAR DISTRICT, BHARUCH, IN-393002, INDIA
EPLERENONE (1000001060)	**AURISCO PHARMACEUTICAL CO. LIMITED**, BADU INDUSTRIAL PARK ZONE, TIANTAI, ZHEJIANG PROVINCE, CN 317200, CHINA
DICLOFENAC SODIUM (2000007774)	**AMOLI ORGANICS PRIVATE LIMITED**, PLOT NO 322/4, 40 SHED AREA, GIDC, VAPI, GUJARAT, IN-396 195, INDIA
WARFARIN SODIUM CLATHRATE (2000006248)	**APOTEX PHARMACHEM INC**, 34-36 SPALDING DRIVE, BRANTFORD ON, N3T 6B8, CANADA **ALEMBIC LIMITED**, PLOT NO. 842-843, VILLAGE- KARAKHADI, TALUK-PADRA, VADODARA, GUJARAT, IN-391 450, INDIA
	CARBOGEN AMCIS AG, HAUPTSTRASSE 171, BUBENDORF, CH-4416, SWITZERLAND
BEXAGLIFLOZIN (1000018985)	**PIRAMAL DIGWAL**, SURVEY NOS. 7-70, 70/1 AND 70/2, DIGWAL VILLAGE, KOHIR MANDAL, KOHIR CROSS ROAD, SANGAREDDY DISTRICT, TELANGANA, IN-502321, INDIA
PREDNISOLONE (1000009794)	**TIANJIN TIANYAO PHARMACEUTICALS CO LIMITED**, 19 XINYE 9TH STREET, WEST AREA OF TIANJIN ECONOMIC TECHNOLOGICAL DEVELOPMENT AREA, TIANJIN, CN-300 462, CHINA

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

FOSTEMSAVIR (1000018194)

PARECOXIB SODIUM (2000005830)

MISOPROSTOL (1000009076)

CANRENOATE POTASSIUM (4000007373)

MISOPROSTOL:HYPROMELLOSE 1:100 DISPERSION (4000014458)

SPIRONOLACTONE (1000009436)

Name and address of the site

MHRA-GMDP MHRA

PIRAMAL HEALTHCARE UK LIMITED, EARLS ROAD, GRANGEMOUTH, FK3 8XG, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance
CLOPROSTENOL SODIUM
2000020722

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallization step
E	General Finishing Steps
	E.1 Physical Processing Steps Drying in vacuum oven
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

CLOPROSTENOL SODIUM (2000020722)

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