

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 5451 |
| 2. Name or corporate name of registrant | CATALENT MICRON TECHNOLOGIES LIMITED |
| 3. Permanent or legal address of registrant | CATALENT MICRON TECHNOLOGIES LIMITED, 8 LEESONS HILL, ST PAULS CRAY, ORPINGTON, BR5 2NH, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | CATALENT MICRON TECHNOLOGIES LIMITED , CROSSWAYS BOULEVARD, CROSSWAYS, DARTFORD, DA2 6QY, 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 | 02/05/2024 |

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

CATALENT MICRON TECHNOLOGIES LIMITED , CROSSWAYS BOULEVARD, CROSSWAYS, DARTFORD, DA2 6QY, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

ILOPERIDONE
1000000868

| | |
|---|--|
| 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 |

Active substance

CLIOQUINOL

1000004182

| | |
|---|--|
| 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 |

Active substance

LOPERAMIDE HYDROCHLORIDE

2000008494

| | |
|---|--|
| 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 |

Active substance

NITISINONE

1000000933

| | |
|---|--|
| 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 |

Active substance

ESTRADIOL HEMIHYDRATE

2000016108

| | |
|---|--|
| 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 |

Active substance

DOLUTEGRAVIR SODIUM

4000014056

| | |
|---|--|
| 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 |

Active substance

MIFEPRISTONE

1000009502

| | |
|---|--|
| 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 |

Active substance

ACLIDINIUM BROMIDE

2000010235

| | |
|---|-------------------------|
| 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 |

Active substance

DASATINIB

1000010690

| | |
|---|--|
| 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 |

Active substance

TRILOSTANE

1000009286

| | |
|---|--|
| 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 |

Active substance

TAZEMETOSTAT

3000018209

| | |
|---|--|
| 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 |

Active substance

SALBUTAMOL SULPHATE

2000007742

| | |
|---|--|
| 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 |

Active substance

FOLIC ACID

1000001996

| | |
|---|--|
| 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 |

Active substance

ISOTRETINOIN

1000008223

| | |
|---|--|
| 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 |

Active substance

LENALIDOMIDE

1000010236

| | |
|---|--|
| E | General Finishing Steps |
| | E.1 Physical Processing Steps Micronisation |
| | E.2 Primary Packaging |
| F | Quality Control Testing |
| | F.1 Physical / Chemical testing |

Active substance

PAZOPANIB HYDROCHLORIDE

2000009969

| | |
|---|--|
| 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 |

Active substance

ARIPIRAZOLE

1000000123

| | |
|---|--|
| 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 |

Active substance

SALICYLIC ACID

1000009710

| | |
|---|-------------------------|
| 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 |

Active substance

APIXABAN

1000011644

| | |
|---|--|
| 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 |

Active substance

TRETINOIN

1000009303

| | |
|---|--|
| E | General Finishing Steps |
| | E.1 Physical Processing Steps Sieving |
| | E.2 Primary Packaging |
| | E.3 Secondary Packaging |
| F | Quality Control Testing |
| | F.1 Physical / Chemical testing |

Active substance

RIMEGEPANT

3000020812

| | |
|---|--|
| 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 |

Active substance

OXYTETRACYCLINE DIHYDRATE

2000008150

| | |
|---|--|
| 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 |

Active substance

AXITINIB

3000013266

| | |
|---|--|
| 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 |

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance 3rd Country Manufacturer

3rd Country Distributor

LLENALIDOMIDE
(1000010236)

LONZA AG, VALAIS WORKS, VISP, CH-3930, SWITZERLAND
CELGENE CHEMICALS SARL, UNTERE BRUEHLSTRASSE 4,
ZOFINGEN, CH-4800, SWITZERLAND

CELGENE CHEMICALS SARL,
UNTERE BRUEHLSTRASSE 4,
ZOFINGEN, CH-4800, SWITZERLAND

ARIPRAZOLE
(1000000123)

OTSUKA PHARMACEUTICAL COMPANY LIMITED, 224-18,
HIRASHI EBISUNO, KAWAUCHI-CHO, TOKUSHIMA, JP-771-0182,
JAPAN

ANTHEM BIOSCIENCES PRIVATE LIMITED, UNIT II NO. 276-P AND 277-P, 20 BANNIKUPPE ROAD, HAROHALLI INDUSTRIAL AREA PHASE II, KANAKPURA TALUK, RAMANAGARA, KARNATAKA, IN-562112, INDIA

RIMEGEPANT
(3000020812)

PIRAMAL PHARMA LIMITED, SURVEY NOS. 7-70, 70/1 AND 70/2, DIGWAL VILLAGE, KOHIR MANDAL, KOHIR CROSS ROAD, SANGAREDDY DISTRICT, TELANGANA, IN-502 321, INDIA

ANTHEM BIOSCIENCES, NO 49 CANARA BANK ROAD, BOMMASANDRA INDUSTRIAL AREA, PHASE 1, HOSUR ROAD, BENGALURU, KARNATAKA, IN-560 099, INDIA

ESCIENTIA ADVANCED SCIENCES PRIVATE LIMITED, PLOT NO. 11, 11A, 12 AND 12A, APSEZ ATCHUTAPURAM, ANAKAPALLI DISTRICT, VISAKHAPATNAM, ANDHRA PRADESH, IN-531011, INDIA

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

ILOPERIDONE (1000000868)

CLIOQUINOL (1000004182)

LOPERAMIDE HYDROCHLORIDE (2000008494)

NITISINONE (1000000933)

ESTRADIOL HEMIHYDRATE (2000016108)

DOLUTEGRAVIR SODIUM (4000014056)

MIFEPRISTONE (1000009502)

ACLIDINIUM BROMIDE (2000010235)

DASATINIB (1000010690)

TRILOSTANE (1000009286)

TAZEMETOSTAT (3000018209)

SALBUTAMOL SULPHATE (2000007742)

FOLIC ACID (1000001996)

ISOTRETINOIN (1000008223)

LENALIDOMIDE (1000010236)

PAZOPANIB HYDROCHLORIDE (2000009969)

ARIPIPRAZOLE (1000000123)

SALICYLIC ACID (1000009710)

APIXABAN (1000011644)

TRETINOIN (1000009303)

RIMEGEPANT (3000020812)

OXYTETRACYCLINE DIHYDRATE (2000008150)

AXITINIB (3000013266)