

# 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
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	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
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	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**

LENALIDOMIDE  
(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

ARIPIPRAZOLE  
(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)

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SALBUTAMOL SULPHATE (2000007742)

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SALICYLIC ACID (1000009710)

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OXYTETRACYCLINE DIHYDRATE (2000008150)

AXITINIB (3000013266)