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	01/06/2026

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

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

1. MANUFACTURING OPERATIONS

Active substance
ARIPIPRAZOLE
1000000123

E	General Finishing Steps
	E.1 Physical Processing Steps Micronisation
	E.2 Primary Packaging

MHRA-GMDP MHRA

	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
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
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

MHRA-GMDP MHRA

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
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
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
TAZEMETOSTAT
3000018209

E	General Finishing Steps

MHRA-GMDP

	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
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
PAZOPANIB HYDROCHLORIDE
2000009969

E	General Finishing Steps
	E.1 Physical Processing Steps Micronisation
	E.2 Primary Packaging

MHRA-GMDP MHRA

	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
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
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

MHRA-GMDP MHRA

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
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
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
ACLIDINIUM BROMIDE
2000010235

E	General Finishing Steps

MHRA-GMDP

	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

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
FOLIC ACID
1000001996

E	General Finishing Steps
	E.1 Physical Processing Steps Micronisation
	E.2 Primary Packaging

MHRA-GMDP MHRA

	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
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

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
ARIPIPRAZOLE (1000000123)	**OTSUKA PHARMACEUTICAL COMPANY LIMITED**, 224-18, HIRASHI EBISUNO, KAWAUCHI-CHO, TOKUSHIMA, JP-771-0182, JAPAN	
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

MHRA-GMDP

PIRAMAL PHARMA LIMITED, SURVEY NOS. 7-70, 70/1 AND 70/2, DIGWAL VILLAGE, KOHIR MANDAL, KOHIR CROSS ROAD, SANGAREDDY DISTRICT, TELANGANA, IN-502321, INDIA

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

RIMEGEPANT (3000020812)

JILIN ASYMCHEM LABORATORIES CO., LIMITED., NO. 99 HONGDA ROAD, ECONOMIC DEVELOPMENT ZONE, DUNHUA, CN-133700, CHINA

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

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

ARIPIPRAZOLE (1000000123)

NITISINONE (1000000933)

SALICYLIC ACID (1000009710)

ILOPERIDONE (1000000868)

TRETINOIN (1000009303)

LENALIDOMIDE (1000010236)

LOPERAMIDE HYDROCHLORIDE (2000008494)

TAZEMETOSTAT (3000018209)

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RIMEGEPANT (3000020812)

SALBUTAMOL SULPHATE (2000007742)

DOLUTEGRAVIR SODIUM (4000014056)

TRILOSTANE (1000009286)

ESTRADIOL HEMIHYDRATE (2000016108)

ACLIDINIUM BROMIDE (2000010235)

AXITINIB (3000013266)

APIXABAN (1000011644)

FOLIC ACID (1000001996)

ISOTRETINOIN (1000008223)

CLIOQUINOL (1000004182)

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