Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 5451 Insp GMP/IMP 5451/16389-0023

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 : CATALENT MICRON TECHNOLOGIES LIMITED

Site address : CATALENT MICRON TECHNOLOGIES LIMITED , CROSSWAYS BOULEVARD, CROSSWAYS, DARTFORD, DA2 6QY, 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 26/06/2025 , 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 :

- [1000009286] TRILOSTANE
- [1000000868] ILOPERIDONE
- [1000009710] SALICYLIC ACID
- [3000018209] TAZEMETOSTAT
- [1000000933] NITISINONE
- [3000020812] RIMEGEPANT

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- [2000010235] ACLIDINIUM BROMIDE
- [2000008150] OXYTETRACYCLINE DIHYDRATE
- [2000008494] LOPERAMIDE HYDROCHLORIDE
- [2000016108] ESTRADIOL HEMIHYDRATE
- [2000007742] SALBUTAMOL SULPHATE
- [1000010236] LENALIDOMIDE
- [2000009969] PAZOPANIB HYDROCHLORIDE
- [3000013266] AXITINIB
- [1000008223] ISOTRETINOIN
- [1000011644] APIXABAN
- [1000010690] DASATINIB
- [1000009303] TRETINOIN
- [1000001996] FOLIC ACID
- [4000014056] DOLUTEGRAVIR SODIUM
- [1000004182] CLIOQUINOL
- [1000000123] ARIPIPRAZOLE
- [1000009502] MIFEPRISTONE

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

TRILOSTANE

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

ILOPERIDONE

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

SALICYLIC ACID

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging

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	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

TAZEMETOSTAT

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

NITISINONE

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

RIMEGEPANT

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

ACLIDINIUM BROMIDE

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging

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3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

OXYTETRACYCLINE DIHYDRATE

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Micronisation

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

LOPERAMIDE HYDROCHLORIDE

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Micronisation

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

ESTRADIOL HEMIHYDRATE

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Micronisation

3.5.2 Primary Packaging

3.5.3 Secondary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

SALBUTAMOL SULPHATE

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
Micronisation

3.5.2 Primary Packaging

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	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

LENALIDOMIDE

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

PAZOPANIB HYDROCHLORIDE

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

AXITINIB

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

ISOTRETINOIN

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging

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3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

APIXABAN

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

DASATINIB

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

TRETINOIN

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Sieving
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

FOLIC ACID

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging

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3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

DOLUTEGRAVIR SODIUM

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

CLIOQUINOL

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

ARIPIPRAZOLE

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

MIFEPRISTONE

3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Micronisation
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging

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3.6	Quality Control Testing
	3.6.1 Physical / Chemical 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 used in combination with the relevant authorisation/registration. A risk-based site inspection programme remains in force.

26/06/2025	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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