

# Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 5451 Insp GMP/IMP 5451/16389-0021

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 21/06/2022 , 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.

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- (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 :

- [1000000868] ILOPERIDONE
- [2000008494] LOPERAMIDE HYDROCHLORIDE
- [1000011644] APIXABAN
- [2000016108] ESTRADIOL HEMIHYDRATE
- [3000013266] AXITINIB
- [1000010690] DASATINIB

- [3000020812] RIMEGEPANT
- [1000004182] CLIOQUINOL
- [2000008150] OXYTETRACYCLINE DIHYDRATE
- [2000007742] SALBUTAMOL SULPHATE
- [2000017501] DABRAFENIB MESYLATE
- [4000014056] DOLUTEGRAVIR SODIUM
- [1000008223] ISOTRETINOIN
- [1000000933] NITISINONE
- [1000009710] SALICYLIC ACID
- [2000010235] ACLIDINIUM BROMIDE
- [2000009969] PAZOPANIB HYDROCHLORIDE
- [1000000123] ARIPIRAZOLE
- [1000009303] TRETINOIN
- [1000009502] MIFEPRISTONE
- [1000010236] LENALIDOMIDE
- [1000009286] TRILOSTANE
- [1000001996] FOLIC ACID

### 3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

#### 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

#### 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

#### 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

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

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

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

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

#### 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

#### 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

#### SALBUTAMOL SULPHATE

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

#### DABRAFENIB MESYLATE

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

#### 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

#### ISOTRETINOIN

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

#### SALICYLIC ACID

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

3.5.3 Secondary 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

#### ARIPIRAZOLE

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

MIFEPRISTONE

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

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

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

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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| 27/07/2022 | Name and signature of the authorised person of the Competent Authority of United Kingdom<br>Confidential<br>Medicines and Healthcare products Regulatory Agency<br>Tel : Confidential |
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