



Medicines & Healthcare products  
Regulatory Agency



**MHRA**

10 South Colonnade  
Canary Wharf  
London  
E14 4PU  
United Kingdom

[gov.uk/mhra](https://www.gov.uk/mhra)

RESTRICTED – COMMERCIAL

Mrs Elizabeth Savage

CONCEPT LIFE SCIENCES INTERGRATED DISCOVERY AND DEVELOPMENT

SERVICES LIMITED

DISCOVERY PARK HOUSE

RAMSGATE ROAD

SANDWICH

CT13 9ND

UNITED KINGDOM



Certificate No: UK API 48975 Insp GMP 48975/19230206-0004

## Medicines and Healthcare products Regulatory Agency

### CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

#### Part 1

**Issued following an inspection in accordance with Regulation 331A of The Human Medicines Regulation 2012 (SI 2012/1916)**

The competent authority of the United Kingdom confirms the following:

|                  |   |
|------------------|---|
| The manufacturer | CONCEPT LIFE SCIENCES INTERGRATED DISCOVERY AND DEVELOPMENT SERVICES LIMITED    |
| Site address     | DISCOVERY PARK HOUSE<br>RAMSGATE ROAD<br>SANDWICH<br>CT13 9ND<br>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 22/06/2021, it is considered that it complies with the principles of GMP for active substances.

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 only valid when presented with all pages and both parts 1 and 2.

The authenticity of this certificate may be verified in MHRA-GMDP database. If it does not appear please contact the issuing authority.



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## Part 2

Human Medicinal Products

### 1. MANUFACTURING OPERATIONS

#### 1.1 Sterile products

Not Authorised

#### 1.2 Non-sterile products

Not Authorised

#### 1.3 Biological medicinal products

Not Authorised

#### 1.4 Other products or manufacturing activity

Not Authorised

#### 1.5 Packaging

Not Authorised

#### 1.6 Quality control testing

Not Authorised

### 2. IMPORTATION OF MEDICINAL PRODUCTS

#### 2.1 Quality control testing of imported medicinal products

Not Authorised

#### 2.2 Batch certification of imported medicinal products

Not Authorised

#### 2.3 Other importation activities

Not Authorised



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## ACTIVE SUBSTANCES FOR CLINICAL TRIALS

### 3. MANUFACTURING OPERATIONS

#### 3.1 **Manufacture of Active Substance by Chemical Synthesis**

- 3.1.1 Manufacture Of Active Substance Intermediates
- 3.1.2 Manufacture Of Crude Active Substance
- 3.1.3 Salt Formation/Purification Steps (e.g. Crystallisation)  
Crystallisation, recrystallisation, filtration, salt formation
- 3.1.4 Other  
Polymorph transformation

#### 3.2 **Processing Activities of Active Substance from Natural Sources**

Not Authorised

#### 3.3 **Manufacture of Active Substance using Biological Processes**

Not Authorised

#### 3.4 **Manufacture of sterile active substance**

Not Authorised

#### 3.5 **General Finishing Steps**

- 3.5.1 Physical Processing Steps  
Crystallisation, recrystallisation, polymorph transformation, filtration, drying
- 3.5.2 Primary Packaging
- 3.5.3 Secondary Packaging

#### 3.6 **Quality Control Testing**

- 3.6.1 Physical / Chemical testing

#### 4 **Other Activities**

Not Authorised



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**Any restrictions or clarifying remarks related to the scope of this certificate:**

Manufacture of APIs for use in clinical trials in B530 and B901 is certified.

1. Building(s)/Area(s)

Manufacture of APIs for use in clinical trials in B530 and B901 is certified.

2. Room(s)

N/A

3. Line(s) Equipment(s)

N/A

4. QC testing

N/A

5. Medicinal Product(s)/IMP(s)

N/A

**Name of the authorised person of the  
Competent Authority of the United Kingdom**

**Dr A J Gray**  
**Head of Inspectorate**  
**inspectionplanning@mhra.gov.uk**

***Date: 19/10/2021***