Medicines & Healthcare products Regulatory Agency

MHRA

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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

Medicines & Healthcare products Regulatory Agency

MHRA

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 5 of the current Veterinary Medicines Regulations

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 RAMSGATE ROAD SANDWICH CT13 9ND UNITED KINGDOM

Is an active substance manufacturer that has been inspected in accordance with Art. 80(1) of Directive 2001/82/EC transposed in the following national legislation: The current Veterinary Medicines Regulations.

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

Veterinary 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