Certificate No: UK API 27830 Insp GMP 27830/119738-0009

MHRA
Regulating Medicines and Medical Devices

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC.

The competent authority of the United Kingdom confirms the following:

The manufacturer	SELCIA LIMITED
Site address	FYFIELD BUSINESS AND RESEARCH PARK FYFIELD ROAD ONGAR CM5 0GS UNITED KINGDOM

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation: The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 28/09/2017, 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 EudraGMDP. If it does not appear please contact the issuing authority.

Medicines and Healthcare Products Regulatory Agency

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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)
Small scale crystallisation
3.1.4 Other
Carbon-14 labelling of APIs for Clinical Trials

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

3.5.2 Primary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

4 Other Activities

Other Activities
Carbon-14 labelling of APIs for Clinical Trials

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

N/A

1. Building(s)/Area(s)

   N/A

2. Room(s)

   Manufacture in Room 134, QC Testing Room 013

3. Line(s) Equipment(s)

   N/A

4. QC testing

   N/A

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

   Preparation and 14C labelling of APIs for Clinical trials

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

Ewan Norton
GMP Inspector
Ewan.Norton@mhra.gov.uk

Date: 05/12/2017