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Medicines & Healthcare products
Regulatory Agency



Certificate No: UK MIA(IMP) 31890 Insp GMP/IMP 31890/383321-0017

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)

The competent authority of the United Kingdom confirms the following:

The manufacturer	ALMAC SCIENCES LIMITED
Site address	ALMAC HOUSE 20 SEAGOE INDUSTRIAL ESTATE CRAIGAVON NORTHERN IRELAND BT63 5QD UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. MIA(IMP) 31890 in accordance with Art. 13 of Directive 2001/20/EC transposed in the following national legislation: The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 21/03/2019, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Regulation B17 of the Human Medicines Regulations 2012 (as amended).

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 Investigational Medicinal Products for phase I, II, III clinical trials

1. MANUFACTURING OPERATIONS

1.1 Sterile products

Not Authorised

1.2 Non-sterile products

1.2.1 Non-sterile products (processing operations for the following dosage forms)

1.2.1.1 Capsules, hard shell

1.2.1.6 Liquids for internal use

1.2.1.8 Other solid dosage forms

1.2.1.17 Other non-sterile medicinal products

Capsules, hard shell and liquids for internal use includes bulk biological drug product.

Other solid dosage forms include bulk biological powders.

1.3 Biological medicinal products

1.3.1 Biological medicinal products

1.3.1.8 Other biological medicinal products

Capsules, hard shell and liquids for internal use includes bulk biological drug product.

Other solid dosage forms include biological powders.

1.4 Other products or manufacturing activity

1.4.1 Manufacture of

1.4.1.3 Other

Radio-Labelled IMPs.

1.5 Packaging

1.5.1 Primary packaging

1.5.1.1 Capsules, hard shell

1.5.1.6 Liquids for internal use

1.5.1.8 Other solid dosage forms

1.5.1.17 Other non-sterile medicinal products

Capsules, hard shell and liquids for internal use includes bulk biological drug product.

Other solid dosage forms include bulk biological powders.

1.6 Quality control testing

1.6.3 Chemical/physical



2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

2.1.3 Chemical/physical

2.2 Batch certification of imported medicinal products

Not Authorised

2.3 Other importation activities

2.3.1 Site of Physical Importation

2.3.2 Importation of Intermediate which undergoes further processing



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3. MANUFACTURING OPERATIONS

- 3.1 Manufacture of Active Substance by Chemical Synthesis**
Not Authorised
- 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**
Not Authorised
- 3.6 Quality Control Testing**
Not Authorised
- 4 Other Activities**
Not Authorised



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

This certificate is issued based on a desk-based assessment of GMP compliance information provided by the manufacturer. A risk-based site inspection programme remains in force.

1. Building(s)/Area(s)
N/A
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: 15/10/2021



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RESTRICTED – COMMERCIAL
Mr Alan Chambers
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