Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 31890 Insp GMP/GDP 31890/383321-0015 [H]

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 : ALMAC SCIENCES LIMITED

Site address : ALMAC SCIENCES LIMITED, ALMAC HOUSE, 20 SEAGOE INDUSTRIAL ESTATE, CRAIGAVON, BT63 5QD, 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 16/12/2019 , 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.

- *(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 :

- [2000017443] URIDINE TRIACETATE
- [2000018682] AMIFAMPRIDINE PHOSPHATE
- [3000017276] SELEXIPAG
- [1000007809] IOBENGUANE
- [1000018046] ACTIVE SUBSTANCES FOR CLINICAL TRIALS

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

URIDINE TRIACETATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture Of Crude Active Substance
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation) crystallisation
3.5	General Finishing Steps
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

AMIFAMPRIDINE PHOSPHATE

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 (eg. Crystallisation) crystallisation
3.5	General Finishing Steps
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)

SELEXIPAG

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 (eg. Crystallisation) crystallisation
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

IOBENGUANE

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 (eg. Crystallisation)
Salt formation

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

3.6.3 Microbiological testing (including sterility testing)

ACTIVE SUBSTANCES FOR CLINICAL TRIALS

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

Radiopharmaceuticals

3.1.2 Manufacture Of Crude Active Substance

Radiopharmaceuticals

3.1.3 Salt Formation/Purification steps (eg. Crystallisation)
crystallisation, distillation, chromatography or similar alternatives
Radiopharmaceuticals

3.5 General Finishing Steps

3.5.1 Physical Processing Steps
micronisation

3.5.2 Primary Packaging

Radiopharmaceuticals

3.5.3 Secondary Packaging

Radiopharmaceuticals

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

Radiopharmaceuticals

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
			QC testing may also be carried out at ALMAC SCIENCES LIMITED site 16997281 - Block A, Breagh Trade Park, Breagh Drive, Portadown, Craigavon, BT63 5XA, United Kingdom, which operates within the scope of the same Quality Management System.	

05/11/2020	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential