Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK MIA 20782 Insp GMP 20782/15328-0020[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 PHARMA SERVICES LIMITED

Site address : ALMAC PHARMA SERVICES LIMITED, SEAGOE INDUSTRIAL ESTATE, PORTADOWN, CRAIGAVON, BT63 5UA, UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. UK MIA 20782 in accordance with Regulation 17 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 16/09/2024 , 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 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

1. MANUFACTURING OPERATIONS

[1.1] Sterile Products

[1.1.3] Batch certification

[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

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[1.2.1.8] Other solid dosage forms

[1.2.1.13] Tablets

[1.2.1.17] Other non-sterile medicinal products

Other solid dosage forms include powders and granules.

[1.2.2] Batch certification

[1.3] Biological medicinal products

[1.3.2] Batch certification

[1.3.2.4] Gene therapy products

[1.3.2.5] Biotechnology products

[1.3.2.6] Human or animal extracted products

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.2] Capsules, soft shell

[1.5.1.8] Other solid dosage forms

[1.5.1.13] Tablets

[1.5.1.17] Other non-sterile medicinal products

Other solid dosage forms include powders and granules.

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

2. IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.2] Microbiological: non-sterility

[2.1.3] Chemical/Physical

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

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[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing

Restrictions or Remarks

MIA(IMP) packaging operations are restricted to open label, non-randomised activities.

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
This GMP certificate is applicable to operations conducted in buildings 1, 1C, 2, 6, 8, 8a, 8b, 14, 14a, 15, 27b.				

09/07/2026	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential

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