

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 31890

2: Name of authorisation holder ALMAC SCIENCES LIMITED

3: Address(es) of manufacturing site(s) ALMAC SCIENCES LIMITED, ALMAC HOUSE, 20 SEAGOE INDUSTRIAL ESTATE, CRAIGAVON, NORTHERN IRELAND, BT63 5QD, UNITED KINGDOM

4: Legally registered address of authorisation holder ALMAC SCIENCES LIMITED, ALMAC HOUSE, 20 SEAGOE INDUSTRIAL ESTATE, CRAIGAVON, NORTHERN IRELAND, BT63 5QD, UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

6: Legal Basis of authorisation Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Confidential

8: Authorisation Date 03/02/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

ALMAC SCIENCES LIMITED, ALMAC HOUSE, 20 SEAGOE INDUSTRIAL ESTATE, CRAIGAVON, NORTHERN IRELAND, BT63 5QD, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile investigational medicinal 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

[1.2.1.15] 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 investigational 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.

[1.5] 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

[1.5.1.15] 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

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.3] Chemical/Physical

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing