Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 20377
2: Name of authorisation holder	ALMAC CLINICAL SERVICES LIMITED
3: Address(es) of manufacturing site(s)	ALMAC CLINICAL SERVICES LIMITED, SEAGOE INDUSTRIAL ESTATE, 9 CHARLESTOWN ROAD, CRAIGAVON, NORTHERN IRELAND, BT63 5PW, UNITED KINGDOM
4: Legally registered address of authorisation holder	ALMAC CLINICAL SERVICES LIMITED, SEAGOE INDUSTRIAL ESTATE, 9 CHARLESTOWN ROAD, CRAIGAVON, NORTHERN IRELAND, BT63 5PW, 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	03/05/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

ALMAC CLINICAL SERVICES LIMITED, SEAGOE INDUSTRIAL ESTATE, 9 CHARLESTOWN ROAD, CRAIGAVON, NORTHERN IRELAND, BT63 5PW, 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

[1.1] Sterile Investigational Medicinal Products

[1.1.3] Batch certification

[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

[1.2.1.8] Other solid dosage forms

[1.2.1.15] Other non-sterile medicinal products

Other solid dosage forms - Placebo Powders blistered for inhalers. Capsules, hard shell includes penicillins, hormones and cytotoxics/Capsules soft shell

[1.2.2] Batch certification

[1.3] Biological investigational medicinal products

[1.3.2] Batch certification

[1.3.2.1] Blood products

[1.3.2.2] Immunological products

[1.3.2.3] Cell therapy products

[1.3.2.4] Gene therapy products

[1.3.2.5] Biotechnology products

[1.3.2.6] Human or animal extracted products

[1.4] Other investigational medicinal products or manufacturing activitiy

[1.4.1] Manufacture of:

[1.4.1.1] Herbal products

[1.4.1.2] Homoeopathic products

[1.4.1.3] Other

Importation of QP certified IMPs from a country on the approved country for import list / Herbal products, Homeopathic products, Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)

Special Requirements

None

[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

[1.5.1.12] Suppositories

[1.5.1.13] Tablets

[1.5.1.15] Other non-sterile medicinal products

Placebo powders blistered for inhalers/Capsules, hard shell,Capsules, soft shell and tablets includes penicillins, hormones and cytotoxics

[1.5.2] Secondary packaging

[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

[2.2] 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

[2.2.3] Biological medicinal products

[2.2.3.1] Blood products

[2.2.3.2] Immunological products

[2.2.3.3] Cell therapy products

[2.2.3.4] Gene therapy products

[2.2.3.5] Biotechnology products

[2.2.3.6] Human or animal extracted products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing

[2.3.3] Biological Active Substance

[2.3.4] Other

Importation of QP certified IMPs from a country on the approved country for import list / Herbal products, Homeopathic products, Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)