

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 10284

2: Name of authorisation holder SHARP CLINICAL SERVICES (UK) LIMITED

3: Address(es) of manufacturing site(s) SHARP CLINICAL SERVICES (UK) LIMITED, UNIT 28, HEADS OF THE VALLEY INDUSTRIAL ESTATE, RHYMNEY, TREDEGAR, NP22 5RL, UNITED KINGDOM

4: Legally registered address of authorisation holder SHARP CLINICAL SERVICES (UK) LIMITED, UNIT 28, HEADS OF THE VALLEY INDUSTRIAL ESTATE, RHYMNEY, TREDEGAR, NP22 5RL, 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 15/07/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

SHARP CLINICAL SERVICES (UK) LIMITED, UNIT 28, HEADS OF THE VALLEY INDUSTRIAL ESTATE, RHYMNEY, TREDEGAR, NP22 5RL, 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 [1.2.2] Batch certification

[1.4] Other investigational medicinal products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.1] Herbal products

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.2] Capsules, soft shell

[1.5.1.3] Chewing gums

[1.5.1.8] Other solid dosage forms

[1.5.1.13] Tablets

[1.5.2] Secondary packaging

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[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

[2.2.3.2] Immunological products

[2.2.3.5] Biotechnology products

[2.2.3.6] Human or animal extracted products

[2.2.3.8] Other biological medicinal products

Microbial derived.

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.4] Other

Importation of QP certified IMPs from a country on the approved country for import list.