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

SHARP CLINICAL SERVICES (UK) LIMITED, UNIT 28, HEADS OF 3: Address(es) of manufacturing site(s)

THE VALLEY INDUSTRIAL ESTATE, RHYMNEY, TREDEGAR,

NP22 5RL, UNITED KINGDOM

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

Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 6: Legal Basis of authorisation

2004 [SI 2004/1031]

Confidential

7: Name of responsible officer of the competent authority of

the member state granting the manufacturing authorisation

4: Legally registered address of authorisation holder

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

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[1.4] Other investigational medicinal products or manufacturing activitiy [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

MHRA: GMDP MHRA

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

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