

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 21878

2: Name of authorisation holder RICHMOND PHARMACOLOGY LIMITED

3: Address(es) of manufacturing site(s) RICHMOND PHARMACOLOGY LIMITED, 1A NEWCOMEN STREET, LONDON, SE1 1YR, UNITED KINGDOM

4: Legally registered address of authorisation holder RICHMOND PHARMACOLOGY LIMITED, ST GEORGE'S HOSPITAL MEDICAL SCHOOL, CRANMER TERRACE, TOOTING, LONDON, SW17 0RE, 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 03/09/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

RICHMOND PHARMACOLOGY LIMITED, 1A NEWCOMEN STREET, LONDON, SE1 1YR, 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 [1.2.1.5] Liquids for external use [1.2.1.6] Liquids for internal use [1.2.1.11] Semi-solids [1.2.1.12] Suppositories

[1.2.1.15] Other non-sterile medicinal products

Manual filling of air-filled soft-shell capsules

[1.2.2] Batch certification

[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

[1.5.1.4] Impregnated matrices

[1.5.1.5] Liquids for external use

[1.5.1.6] Liquids for internal use

[1.5.1.8] Other solid dosage forms

[1.5.1.11] Semi-solids

[1.5.1.12] Suppositories

[1.5.1.13] Tablets

[1.5.1.14] Transdermal patches

[1.5.1.15] Other non-sterile medicinal products

Pessaries

[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

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing

[2.3.4] Other

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