

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

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|---|--|
| <b>1: Authorisation Number</b>  | UK MIA(IMP) 21878  |
| <b>2: Name of authorisation holder</b>  | RICHMOND PHARMACOLOGY LIMITED  |
| <b>3: Address(es) of manufacturing site(s)</b>  | RICHMOND PHARMACOLOGY LIMITED, 1A NEWCOMEN STREET,<br>LONDON, SE1 1YR, UNITED KINGDOM  |
| <b>4: Legally registered address of authorisation holder</b>  | RICHMOND PHARMACOLOGY LIMITED, ST GEORGE'S HOSPITAL<br>MEDICAL SCHOOL, CRANMER TERRACE, TOOTING, LONDON,<br>SW17 0RE, UNITED KINGDOM |
| <b>5: Scope of authorisation and dosage forms</b>   | ANNEX 1 and/ or ANNEX 2  |
| <b>6: Legal Basis of authorisation</b>  | Part 6 of The Medicines for Human Use (Clinical Trials) Regulations<br>2004 [SI 2004/1031]   |
| <b>7: Name of responsible officer of the competent authority<br/>of the member state granting the manufacturing<br/>authorisation</b> | Confidential   |
| <b>8: Authorisation Date</b>  | 25/09/2024   |
| <b>9: Annexes attached</b>  | 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

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| Human Investigational Medicinal Products   |
| Authorised Operations  |
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)  |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.2 ] Non-sterile investigational medicinal products</b><br>[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)<br>[ 1.2.1.1 ] Capsules, hard shell<br>[ 1.2.1.5 ] Liquids for external use<br>[ 1.2.1.6 ] Liquids for internal use<br>[ 1.2.1.11 ] Semi-solids<br>[ 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