

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA(IMP) 5866

**2: Name of authorisation holder** GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED

**3: Address(es) of manufacturing site(s)** GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED, THIRD AVENUE, HARLOW, CM19 5AW, UNITED KINGDOM  
GLAXOSMITHKLINE RESEARCH & DEVELOPMENT, HARRIS'S LANE, WARE, SG12 0GX, UNITED KINGDOM  
GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED, ADDENBROOKE'S HOSPITAL BOX 128, CLINICAL RESEARCH UNIT, HILLS ROAD, CAMBRIDGE, CB2 0GG, UNITED KINGDOM

**4: Legally registered address of authorisation holder** GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED, 79 NEW OXFORD STREET, LONDON, WC1A 1DG, 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** 04/06/2025

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED**, THIRD AVENUE, HARLOW, CM19 5AW, 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>[ 1.1 ] Sterile Investigational Medicinal Products</b><br>[ 1.1.3 ] Batch certification |

**[ 1.2 ] Non-sterile investigational medicinal products**

[ 1.2.2 ] Batch certification

**[ 1.3 ] Biological investigational medicinal products**

[ 1.3.2 ] Batch certification

[ 1.3.2.5 ] Biotechnology products

**[ 1.5 ] Packaging**

[ 1.5.1 ] Primary packaging

[ 1.5.1.1 ] Capsules, hard shell

[ 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

[ 2.2.3.5 ] Biotechnology products

[ 2.2.3.8 ] Other biological medicinal products

Synthetic Proteins

**[ 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

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

**SCOPE OF AUTHORISATION**

**Annex 2**

Name and address of the site:

**GLAXOSMITHKLINE RESEARCH & DEVELOPMENT, HARRIS'S LANE, WARE, SG12 0GX, UNITED KINGDOM**

|  |
|--|
| Human Investigational Medicinal Products       |
| Authorised Operations                          |
| MANUFACTURING OPERATIONS (according to part 1) |

**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

[ 1.2.1.8 ] Other solid dosage forms

[ 1.2.1.13 ] Tablets

[ 1.2.1.15 ] Other non-sterile medicinal products

Solid non-sterile multi dose forms (including powders and granules), powder inhalation products and devices.

[ 1.2.2 ] Batch certification

**[ 1.6 ] Quality control testing**

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.3 ] Chemical/Physical

**SCOPE OF AUTHORISATION**

**Annex 2**

Name and address of the site:

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Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

**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

[ 1.2.1.15 ] Other non-sterile medicinal products

Powder in bottle

[ 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

[ 1.5.1.5 ] Liquids for external use

[ 1.5.1.6 ] Liquids for internal use

[ 1.5.1.13 ] Tablets

[ 1.5.2 ] Secondary packaging