

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 5866
<b>2: Name of authorisation holder</b>	GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED, ADDENBROOKE'S HOSPITAL BOX 128, CLINICAL RESEARCH UNIT, HILLS ROAD, CAMBRIDGE, CB2 0GG, UNITED KINGDOM
<b>3: Address(es) of manufacturing site(s)</b>	GLAXOSMITHKLINE RESEARCH & DEVELOPMENT, HARRIS'S LANE, WARE, SG12 0GX, UNITED KINGDOM  GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED, THIRD AVENUE, HARLOW, CM19 5AW, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED, GSK HOUSE, 980 GREAT WEST ROAD, BRENTFORD, TW8 9GS, 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 2004 [SI 2004/1031]
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	27/06/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED**, ADDENBROOKE'S HOSPITAL BOX 128, CLINICAL RESEARCH UNIT, HILLS ROAD, CAMBRIDGE, CB2 0GG, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.2 ] Non-sterile investigational medicinal products</b> [ 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
- [ 1.2.1.15 ] Other non-sterile medicinal products
  - Powder in bottle

**[ 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
  - [ 1.5.1.11 ] Semi-solids
  - [ 1.5.1.13 ] Tablets
- [ 1.5.2 ] Secondary packaging

**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:

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**

[ 1.2.2 ] 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**

[ 2.3.4 ] Other

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