# 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

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

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

3: Address(es) of manufacturing site(s)

manufacturing authorisation

Confidential

8: Authorisation Date 24/10/2025

**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

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

Issue Date: 24 Oct 2025

# [ 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

Issue Date: 24 Oct 2025

[ 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

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#### 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)

# 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

Issue Date: 24 Oct 2025