

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, 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, THIRD AVENUE, HARLOW, CM19 5AW, UNITED KINGDOM

5: Scope of authorisation and dosage forms GLAXOSMITHKLINE RESEARCH & DEVELOPMENT, HARRIS'S LANE, WARE, SG12 0GX, UNITED KINGDOM

6: Legal Basis of authorisation ANNEX 1 and/ or ANNEX 2

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]

8: Authorisation Date Confidential

9: Annexes attached 14/03/2025

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)
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

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 <ul style="list-style-type: none"> [1.1.3] Batch certification [1.2] Non-sterile investigational medicinal products <ul style="list-style-type: none"> [1.2.2] Batch certification [1.3] Biological investigational medicinal products <ul style="list-style-type: none"> [1.3.2] Batch certification <ul style="list-style-type: none"> [1.3.2.5] Biotechnology products [1.5] Packaging <ul style="list-style-type: none"> [1.5.1] Primary packaging <ul style="list-style-type: none"> [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 <ul style="list-style-type: none"> [2.2.1] Sterile Products <ul style="list-style-type: none"> [2.2.1.1] Aseptically prepared

<ul style="list-style-type: none"> [2.2.1.2] Terminally sterilised [2.2.2] Non-sterile products [2.2.3] Biological medicinal products <ul style="list-style-type: none"> [2.2.3.5] Biotechnology products [2.2.3.8] Other biological medicinal products Synthetic Proteins
[2.3] Other Importation Activities <ul style="list-style-type: none"> [2.3.1] Site of Physical Importation [2.3.2] Importation of Intermediate which undergoes further processing [2.3.4] Other <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) <ul style="list-style-type: none"> [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 <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> [1.6.2] Microbiological: non-sterility [1.6.3] Chemical/Physical