

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, ADDENBROOKE'S HOSPITAL BOX 128, CLINICAL RESEARCH UNIT, HILLS ROAD, CAMBRIDGE, CB2 0GG, UNITED KINGDOM
3: Address(es) of manufacturing site(s)	GLAXOSMITHKLINE RESEARCH & DEVELOPMENT, HARRIS'S LANE, WARE, SG12 0GX, UNITED KINGDOM GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED, THIRD AVENUE, HARLOW, CM19 5AW, UNITED KINGDOM
4: Legally registered address of authorisation holder	GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED, GSK HOUSE, 980 GREAT WEST ROAD, BRENTFORD, TW8 9GS, 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	27/06/2024
9: Annexes attached	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
- [1.2.1.11] 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
<p>MANUFACTURING OPERATIONS (according to part 1)</p> <p>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)</p>
<p>Part 1 - MANUFACTURING OPERATIONS</p> <p>[1.1] Sterile Investigational Medicinal Products</p> <p>[1.1.3] Batch certification</p> <p>[1.2] Non-sterile investigational medicinal products</p> <p>[1.2.2] Batch certification</p> <p>[1.3] Biological investigational medicinal products</p> <p>[1.3.2] Batch certification</p> <p>[1.3.2.5] Biotechnology products</p> <p>[1.5] Packaging</p> <p>[1.5.1] Primary packaging</p> <p>[1.5.1.1] Capsules, hard shell</p> <p>[1.5.1.13] Tablets</p> <p>[1.5.2] Secondary packaging</p> <p>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</p> <p>[2.2] Batch certification of imported medicinal products</p> <p>[2.2.1] Sterile Products</p> <p>[2.2.1.1] Aseptically prepared</p> <p>[2.2.1.2] Terminally sterilised</p> <p>[2.2.2] Non-sterile products</p> <p>[2.2.3] Biological medicinal products</p> <p>[2.2.3.5] Biotechnology products</p> <p>[2.2.3.8] Other biological medicinal products</p> <p>Synthetic Proteins</p> <p>[2.3] Other Importation Activities</p> <p>[2.3.4] Other</p> <p>Authorised for Importation of QP certified IMPs from a country on the approved country for import list.</p>