Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 4

2: Name of authorisation holder GLAXO OPERATIONS UK LIMITED

GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS, PRIORY STREET, WARE, SG12 0DJ, UNITED

KINGDOM

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

GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME

OPERATIONS, HARMIRE ROAD, BARNARD CASTLE, DL12 8DT,

UNITED KINGDOM

4: Legally registered address of authorisation holder

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]

Confidential

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

8: Authorisation Date 17/09/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS, PRIORY STREET, WARE, SG12 0DJ, 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

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[1.2.1.13] Tablets [1.2.1.15] Other non-sterile medicinal products Licensable Medicinal Devices [1.3] Biological investigational medicinal products [1.3.1] Biological medicinal products [1.3.1.8] Other biological medicinal products Steroids. [1.4] Other investigational medicinal products or manufacturing activitiy [1.4.3] Other Micronisation of Active Substances [1.5] Packaging [1.5.1] Primary packaging [1.5.1.1] Capsules, hard shell [1.5.1.8] Other solid dosage forms [1.5.1.13] Tablets [1.5.1.15] Other non-sterile medicinal products Licensable Medical Devices [1.5.2] Secondary packaging [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:

GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS, HARMIRE ROAD, BARNARD CASTLE, DL12 8DT, 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

[1.1.1] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.1] Large volume liquids

[1.1.1.4] Small volume liquids

[1.1.2] Terminally Sterilised (processing operations for the following dosage forms)

[1.1.2.1] Large volume liquids

[1.1.2.3] Small volume liquids

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[1.1.2.5] Other terminally sterilised prepared products
Manufacture of parametrically released products where authorised by the individual Marketing Authorisation
[1.1.3] Batch certification
[1.2] Non-sterile investigational medicinal products
[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)
[1.2.1.11] Semi-solids
[1.2.2] Batch certification
[1.3] Biological investigational medicinal products
[1.3.1] Biological medicinal products
[1.3.2] Batch certification
[1.3.2.5] Biotechnology products
[1.3.2.5] Biotechnology products
[1.4.2] Other investigational medicinal products or manufacturing activitiy
[1.4.2] Sterilisation of active substances/excipients/finished products:
[1.4.2.1] Filtration

[1.5] Packaging

[1.5.1] Primary packaging

[1.4.2.3] Moist heat

[1.5.1.11] Semi-solids

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.1] Microbiological: sterility

[1.6.2] Microbiological: non-sterility

Manufacturer's Authorisation: UK MIA(IMP) 4

[1.6.3] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.3] Chemical/Physical



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