

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

3: Address(es) of manufacturing site(s) GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS, PRIORY STREET, WARE, SG12 0DJ, UNITED KINGDOM

4: Legally registered address of authorisation holder GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS, HARMIRE ROAD, BARNARD CASTLE, DL12 8DT, UNITED KINGDOM

5: Scope of authorisation and dosage forms GLAXO OPERATIONS UK LIMITED, 79 NEW OXFORD STREET, LONDON, WC1A 1DG, 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 09/06/2026

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

[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 activity

[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)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

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

[1.1.1.4] Small volume liquids

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

[1.1.2.3] Small volume liquids

[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

[1.3.1.2] Immunological products

[1.3.1.5] Biotechnology products

[1.3.2] Batch certification

[1.3.2.2] Immunological products

[1.3.2.5] Biotechnology products

[1.4] Other investigational medicinal products or manufacturing activity

[1.4.2] Sterilisation of active substances/excipients/finished products:

[1.4.2.1] Filtration

[1.4.2.3] Moist heat

[1.5] Packaging

[1.5.1] Primary packaging

[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

[1.6.3] Chemical/Physical