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 GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS, HARMIRE ROAD, BARNARD CASTLE, DL12 8DT, UNITED KINGDOM
4: Legally registered address of authorisation holder	GLAXO OPERATIONS UK LIMITED, 79 NEW 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 manufacturing authorisation	Confidential
8: Authorisation Date	09/06/2026
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

MHRA-GMDP

[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)

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

MHRA-GMDP MHRA

[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 activitiy

[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

MHRA-GMDP MHRA