

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, HARMIRE ROAD, BARNARD CASTLE, DL12 8DT, UNITED KINGDOM

4: Legally registered address of authorisation holder GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS, PRIORY STREET, WARE, SG12 0DJ, 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 22/04/2025

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, 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

<ul style="list-style-type: none"> [1.1.1.4] Small volume liquids
[1.1.2] Terminally Sterilised (processing operations for the following dosage forms)
<ul style="list-style-type: none"> [1.1.2.1] Large volume liquids
<ul style="list-style-type: none"> [1.1.2.3] Small volume liquids
<ul style="list-style-type: none"> [1.1.2.5] Other terminally sterilised prepared products
<ul style="list-style-type: none"> <ul style="list-style-type: none"> 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)
<ul style="list-style-type: none"> [1.2.1.11] Semi-solids
[1.2.2] Batch certification
[1.3] Biological investigational medicinal products
[1.3.1] Biological medicinal products
<ul style="list-style-type: none"> [1.3.1.5] Biotechnology products
[1.3.2] Batch certification
<ul style="list-style-type: none"> [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:
<ul style="list-style-type: none"> [1.4.2.1] Filtration
<ul style="list-style-type: none"> [1.4.2.3] Moist heat
[1.5] Packaging
[1.5.1] Primary packaging
<ul style="list-style-type: none"> [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
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS
[2.1] Quality control testing of imported medicinal products
<ul style="list-style-type: none"> [2.1.3] Chemical/Physical

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