

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 4
<b>2: Name of authorisation holder</b>	GLAXO OPERATIONS UK LIMITED GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS, NORTH LONSDALE ROAD, ULVERSTON, LA12 9DR, UNITED KINGDOM GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS, HARMIRE ROAD, BARNARD CASTLE, DL12 8DT, UNITED KINGDOM
<b>3: Address(es) of manufacturing site(s)</b>	GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS, HARMIRE ROAD, BARNARD CASTLE, DL12 8DT, UNITED KINGDOM GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS, PRIORITY STREET, WARE, SG12 0DJ, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	GLAXO OPERATIONS UK LIMITED, 980 GREAT WEST ROAD, BRENTFORD, TW8 9GS, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	12/03/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS**, NORTH LONSDALE ROAD, ULVERSTON, LA12 9DR, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

**Part 1 - MANUFACTURING OPERATIONS**

**[ 1.2 ] Non-sterile products**

[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)

[ 1.2.1.8 ] Other solid dosage forms

**Special Requirements**

by extrusion/cephalosporins, beta lactam antibiotics

**[ 1.6 ] Quality control testing**

[ 1.6.3 ] Chemical/Physical

**SCOPE OF AUTHORISATION**

**Annex 1**

Name and address of the site:

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

Human 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 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

[ 1.1.2.5 ] 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 products**

[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)

[ 1.2.1.6 ] Liquids for internal use

[ 1.2.1.11 ] Semi-solids

[ 1.2.1.17 ] Other non-sterile medicinal products

Licensable Medical Devices

[ 1.2.2 ] Batch certification

**[ 1.3 ] Biological medicinal products**

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.2 ] Immunological products

[ 1.3.1.5 ] Biotechnology products

[ 1.3.1.8 ] Other biological medicinal products  
Steroids, Antibacterial Agents, Antifungal Agents

[ 1.3.2 ] Batch certification

[ 1.3.2.2 ] Immunological products

[ 1.3.2.5 ] Biotechnology products

[ 1.3.2.8 ] Other biological medicinal products

Steroids, Antibacterial Agents, Antifungal Agents

**[ 1.4 ] Other products or manufacturing activity**

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

[ 1.4.2.1 ] Filtration

[ 1.4.2.2 ] Dry heat

[ 1.4.2.3 ] Moist heat

**[ 1.5 ] Packaging**

[ 1.5.1 ] Primary packaging

[ 1.5.1.6 ] Liquids for internal use

[ 1.5.1.11 ] Semi-solids

[ 1.5.1.17 ] Other non-sterile medicinal products

Licensable Medical Devices

[ 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

[ 1.6.4 ] Biological

**Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**

**[ 2.1 ] Quality control testing of imported medicinal products**

[ 2.1.1 ] Microbiological: sterility

[ 2.1.2 ] Microbiological: non-sterility

[ 2.1.3 ] Chemical/Physical

**[ 2.2 ] Batch certification of imported medicinal products**

[ 2.2.1 ] Sterile Products

[ 2.2.1.1 ] Aseptically prepared

[ 2.2.1.2 ] Terminally sterilised

[ 2.2.2 ] Non-sterile products

[ 2.2.3 ] Biological medicinal products

[ 2.2.3.5 ] Biotechnology products

**[ 2.3 ] Other Importation Activities**

[ 2.3.2 ] Importation of Intermediate which undergoes further processing

[ 2.3.3 ] Biological Active Substance

**SCOPE OF AUTHORISATION**

**Annex 1**

Name and address of the site:

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.2 ] Non-sterile products</b> [ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms) [ 1.2.1.8 ] Other solid dosage forms <b>Special Requirements</b> cephalosporins, beta lactam antibiotics [ 1.2.1.13 ] Tablets <b>Special Requirements</b> cephalosporins, beta lactam antibiotics [ 1.2.1.17 ] Other non-sterile medicinal products cephalosporins, beta lactam antibiotics [ 1.2.2 ] Batch certification <b>[ 1.5 ] Packaging</b> [ 1.5.1 ] Primary packaging [ 1.5.1.8 ] Other solid dosage forms <b>Special Requirements</b> cephalosporins, beta lactam antibiotics [ 1.5.1.13 ] Tablets <b>Special Requirements</b> cephalosporins, beta lactam antibiotics [ 1.5.1.17 ] Other non-sterile medicinal products cephalosporins, beta lactam antibiotics [ 1.5.2 ] Secondary packaging <b>[ 1.6 ] Quality control testing</b> [ 1.6.3 ] Chemical/Physical Part 2 - IMPORTATION OF MEDICINAL PRODUCTS <b>[ 2.1 ] Quality control testing of imported medicinal products</b> [ 2.1.3 ] Chemical/Physical

**SCOPE OF AUTHORISATION**

**Annex 1**

Name and address of the site:

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

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

**Part 1 - MANUFACTURING OPERATIONS**

**[ 1.2 ] Non-sterile 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
  - [ 1.2.1.17 ] Other non-sterile medicinal products
    - Licensable medical devices

**[ 1.3 ] Biological medicinal products**

- [ 1.3.1 ] Biological medicinal products
  - [ 1.3.1.8 ] Other biological medicinal products
    - Steroids

**[ 1.4 ] Other products or manufacturing activity**

- [ 1.4.1 ] Manufacture of:
  - [ 1.4.1.3 ] 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
  - [ 1.5.1.17 ] 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