Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 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, 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 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, PRIORY STREET, WARE, SG12 0DJ, UNITED KINGDOM
4: Legally registered address of authorisation holder	GLAXO OPERATIONS UK LIMITED, 980 GREAT WEST ROAD, BRENTFORD, TW8 9GS, UNITED KINGDOM
5: Scope of authorisation and dosage forms	ANNEX 1 and/ or ANNEX 2
6: Legal Basis of authorisation	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	12/03/2024
9: Annexes attached	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:

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

[1.2] 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

cephalosporins, beta lactam antibiotics

[1.2.1.13] Tablets

Special Requirements

cephalosporins, beta lactam antibiotics

[1.2.1.17] Other non-sterile medicinal products

cephalosporins, beta lactam antibiotics

[1.2.2] Batch certification

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.8] Other solid dosage forms

Special Requirements

cephalosporins, beta lactam antibiotics

[1.5.1.13] Tablets

Special Requirements

cephalosporins, beta lactam antibiotics

[1.5.1.17] Other non-sterile medicinal products

cephalosporins, beta lactam antibiotics

[1.5.2] Secondary packaging

[1.6] Quality control testing

[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

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