

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

|   |   |
|---|---|
| <b>1: Authorisation Number</b>  | UK MIA(IMP) 4   |
| <b>2: Name of authorisation holder</b>  | GLAXO OPERATIONS UK LIMITED<br>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, PRIORY STREET, WARE, SG12 0DJ, UNITED KINGDOM   |
| <b>4: Legally registered address of authorisation holder</b>  | GLAXO OPERATIONS UK LIMITED, 79 NEW OXFORD STREET, LONDON, WC1A 1DG, UNITED KINGDOM   |
| <b>5: Scope of authorisation and dosage forms</b>   | ANNEX 1 and/ or ANNEX 2   |
| <b>6: Legal Basis of authorisation</b>  | Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]   |
| <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>  | 16/01/2025  |
| <b>9: Annexes attached</b>  | 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

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| Human Investigational Medicinal Products   |
| Authorised Operations  |
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)  |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Investigational Medicinal Products</b><br>[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)<br>[ 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
    - [ 1.1.2.3 ] 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
      - [ 1.3.1.5 ] Biotechnology products
    - [ 1.3.2 ] Batch certification
      - [ 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
- Part 2 - IMPORTATION OF MEDICINAL PRODUCTS
- [ 2.1 ] Quality control testing of imported medicinal products**
    - [ 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