

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA 5866

**2: Name of authorisation holder** GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED

**3: Address(es) of manufacturing site(s)** GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED,  
THIRD AVENUE, HARLOW, CM19 5AW, UNITED KINGDOM

**4: Legally registered address of authorisation holder** GLAXOSMITHKLINE RESEARCH & DEVELOPMENT 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** 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** 04/06/2025

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED**, THIRD AVENUE, HARLOW, CM19 5AW, UNITED KINGDOM

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>[ 1.1 ] Sterile Products</b> [ 1.1.3 ] Batch certification <b>[ 1.2 ] Non-sterile products</b> [ 1.2.2 ] Batch certification <b>[ 1.3 ] Biological medicinal products</b> [ 1.3.2 ] Batch certification [ 1.3.2.5 ] Biotechnology products <b>[ 1.5 ] Packaging</b>

- [ 1.5.1 ] Primary packaging
  - [ 1.5.1.1 ] Capsules, hard shell
  - [ 1.5.1.13 ] Tablets
- [ 1.5.2 ] Secondary packaging

## Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

### [ 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
  - [ 2.2.3.8 ] Other biological medicinal products
- Synthetic proteins

### [ 2.3 ] Other Importation Activities

- [ 2.3.1 ] Site of Physical Importation
- [ 2.3.2 ] Importation of Intermediate which undergoes further processing