

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)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Products [1.1.3] Batch certification [1.2] Non-sterile products [1.2.2] Batch certification [1.3] Biological medicinal products [1.3.2] Batch certification [1.3.2.5] Biotechnology products [1.5] Packaging

- [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