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	22/04/2026
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

MHRA-GMDP MHRA

[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

MHRA-GMDP MHRA MHRA-GMDP MHRA