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

THIRD AVENUE, HARLOW, CIVITY SAW, UNITED KINGDOW

GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED,
4: Legally registered address of authorisation holder 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

8: Authorisation Date 24/10/2025

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

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[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

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