

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 4416
2: Name of authorisation holder	SANDOZ LIMITED
3: Address(es) of manufacturing site(s)	SANDOZ LIMITED, PARK VIEW, RIVERSIDE WAY, WATCHMOOR PARK, CAMBERLEY, GU15 3YL, UNITED KINGDOM SANDOZ LIMITED , MAXIS 1, WESTERN ROAD, BRACKNELL, RG12 1RF, UNITED KINGDOM SANDOZ LIMITED, PARK VIEW, RIVERSIDE WAY, WATCHMOOR PARK, CAMBERLEY, GU15 3YL, UNITED KINGDOM
4: Legally registered address of authorisation holder	SANDOZ LIMITED, PARK VIEW, RIVERSIDE WAY, WATCHMOOR PARK, CAMBERLEY, GU15 3YL, 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	21/11/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

SANDOZ LIMITED, PARK VIEW, RIVERSIDE WAY, WATCHMOOR PARK, CAMBERLEY, GU15 3YL, 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

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

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

SANDOZ LIMITED , MAXIS 1, WESTERN ROAD, BRACKNELL, RG12 1RF, 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

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