

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

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 09/05/2024

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