Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number **UK MIA 4416**

SANDOZ LIMITED 2: Name of authorisation holder

SANDOZ LIMITED, PARK VIEW, RIVERSIDE WAY, 3: Address(es) of manufacturing site(s)

WATCHMOOR PARK, CAMBERLEY, GU15 3YL, UNITED

KINGDOM

SANDOZ LIMITED, PARK VIEW, RIVERSIDE WAY,

4: Legally registered address of authorisation holder WATCHMOOR PARK, CAMBERLEY, GU15 3YL, UNITED

KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI 6: Legal Basis of authorisation

2012/1916)

7: Name of responsible officer of the competent authority of the

member state granting the manufacturing authorisation

Confidential

8: Authorisation Date 12/03/2024

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

Issue Date: 12 Mar 2024

