Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 58839

2: Name of authorisation holder ZYDUS PHARMACEUTICALS UK LTD

ZYDUS PHARMACEUTICALS UK LIMITED, OFFICE ZPUK,SANDRETTO

3: Address(es) of manufacturing site(s) BUILDING, CAVALRY HILL INDUSTRIAL PARK, WEEDON,

NORTHAMPTON, NN7 4PP, UNITED KINGDOM

4: Legally registered address of authorisation holder

TEMPLE BACK, BRISTOL, BS1 6FL, 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 21/11/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ZYDUS PHARMACEUTICALS UK LIMITED, OFFICE ZPUK, SANDRETTO BUILDING, CAVALRY HILL INDUSTRIAL PARK, WEEDON, NORTHAMPTON, NN7 4PP, 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

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

Issue Date: 21 Nov 2025

