

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 58839

2: Name of authorisation holder ZYDUS PHARMACEUTICALS UK LTD

3: Address(es) of manufacturing site(s) ZYDUS PHARMACEUTICALS UK LIMITED, OFFICE ZPUK, SANDRETTO BUILDING, CAVALRY HILL INDUSTRIAL PARK, WEEDON, NORTHAMPTON, NN7 4PP, UNITED KINGDOM

4: Legally registered address of authorisation holder ZYDUS PHARMACEUTICALS UK LIMITED, OFFICE 1, OLD ART COLLEGE, 12 FREDERICK STREET, LOUGHBOROUGH, LE11 3BJ, UNITED KINGDOM

5: Scope of authorisation and dosage forms ZYDUS PHARMACEUTICALS UK LTD, 1ST FLOOR, TEMPLEBACK, 10 TEMPLE BACK, BRISTOL, BS1 6FL, UNITED KINGDOM

6: Legal Basis of authorisation ANNEX 1 and/ or ANNEX 2

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

8: Authorisation Date Confidential

9: Annexes attached 09/05/2025

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

[2.2.2] Non-sterile products

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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

[2.2.2] Non-sterile products