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 LTD, OFFICE ZPUK,SANDRETTO BUILDING, CAVALRY HILL INDUSTRIAL PARK, WEEDON, NORTHAMPTON, NN7 4PP, UNITED KINGDOM
4: Legally registered address of authorisation holder	ZYDUS PHARMACEUTICALS UK LTD, 1ST FLOOR, TEMPLEBACK, 10 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	28/01/2026
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ZYDUS PHARMACEUTICALS UK LTD, 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