Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 56253

2: Name of authorisation holder IDORSIA PHARMACEUTICALS UK LIMITED

IDORSIA PHARMACEUTICALS UK LIMITED, 20

EASTBOURNE TERRACE, LONDON, W2 6LG, UNITED

KINGDOM

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EASTBOURNE TERRACE, LONDON, W2 6LG, UNITED

KINGDOM

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

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

4: Legally registered address of authorisation holder

Confidential

8: Authorisation Date

6: Legal Basis of authorisation

09/01/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

3: Address(es) of manufacturing site(s)

Annex 1

Name and address of the site:

IDORSIA PHARMACEUTICALS UK LIMITED, 20 EASTBOURNE TERRACE, LONDON, W2 6LG, 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

[1.2] Non-sterile products

[1.2.2] Batch certification

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

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