Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number **UK MIA 35507**

2: Name of authorisation holder LUPIN HEALTHCARE (UK) LIMITED

LUPIN HEALTHCARE (UK) LIMITED, THE URBAN BUILDING, 3: Address(es) of manufacturing site(s)

2ND FLOOR, 3-9 ALBERT STREET, SLOUGH, SL1 2BE,

UNITED KINGDOM

LUPIN HEALTHCARE (UK) LIMITED, THE URBAN BUILDING,

2ND FLOOR, 3-9 ALBERT STREET, SLOUGH, SL1 2BE,

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

22/04/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

LUPIN HEALTHCARE (UK) LIMITED, THE URBAN BUILDING, 2ND FLOOR, 3-9 ALBERT STREET, SLOUGH, SL1 2BE, 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

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