

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 35507
2: Name of authorisation holder	LUPIN HEALTHCARE (UK) LIMITED
3: Address(es) of manufacturing site(s)	LUPIN HEALTHCARE (UK) LIMITED, THE URBAN BUILDING, 2ND FLOOR, 3-9 ALBERT STREET, SLOUGH, SL1 2BE, UNITED KINGDOM
4: Legally registered address of authorisation holder	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
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	14/03/2024
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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Products</b> [ 1.1.3 ] Batch certification <b>[ 1.2 ] Non-sterile products</b> [ 1.2.2 ] Batch certification <b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b> <b>[ 2.2 ] Batch certification of imported medicinal products</b> [ 2.2.1 ] Sterile Products



[ 2.2.1.1 ] Aseptically prepared

[ 2.2.1.2 ] Terminally sterilised

[ 2.2.2 ] Non-sterile products

[ 2.2.3 ] Biological medicinal products

[ 2.2.3.5 ] Biotechnology products

[ 2.2.3.8 ] Other biological medicinal products

Recombinant product - Biosimilar