

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 50827

2: Name of authorisation holder LUYE PHARMA LIMITED

3: Address(es) of manufacturing site(s) LUYE PHARMA LIMITED, SURREY TECHNOLOGY CENTRE, 40 OCCAM ROAD, SURREY RESEARCH PARK, GUILDFORD, GU2 7YG, UNITED KINGDOM

4: Legally registered address of authorisation holder LUYE PHARMA LIMITED, SURREY TECHNOLOGY CENTRE, 40 OCCAM ROAD, SURREY RESEARCH PARK, GUILDFORD, GU2 7YG, 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 19/05/2026

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

LUYE PHARMA LIMITED, SURREY TECHNOLOGY CENTRE, 40 OCCAM ROAD, SURREY RESEARCH PARK, GUILDFORD, GU2 7YG, 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 [1.3] Biological medicinal products [1.3.2] Batch certification [1.3.2.5] Biotechnology products 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