

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 39

2: Name of authorisation holder UCB PHARMA LIMITED

UCB PHARMA LIMITED, 208 BATH ROAD, SLOUGH, SL1 3WE, UNITED KINGDOM

3: Address(es) of manufacturing site(s) UCB PHARMA LIMITED, WINDLESHAM CAMPUS, SUNNINGHILL ROAD, WINDLESHAM, GU20 6PP, UNITED KINGDOM

4: Legally registered address of authorisation holder UCB PHARMA LIMITED, 208 BATH ROAD, SLOUGH, SL1 3WE, 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 21/08/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

UCB PHARMA LIMITED, 208 BATH ROAD, SLOUGH, SL1 3WE, 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

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

UCB PHARMA LIMITED, WINDLESHAM CAMPUS, SUNNINGHILL ROAD, WINDLESHAM, GU20 6PP, 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