

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 42289

2: Name of authorisation holder WAVE PHARMA LIMITED

3: Address(es) of manufacturing site(s) WAVE PHARMA LIMITED, GROUND FLOOR, CAVENDISH HOUSE, 369 BURNT OAK BROADWAY, EDGWARE, HA8 5AW, UNITED KINGDOM

4: Legally registered address of authorisation holder MAWDSLEY-BROOKS & COMPANY LIMITED, UNIT 22, QUEST PARK, WHEATLEY HALL ROAD, DONCASTER, DN2 4LT, UNITED KINGDOM

5: Scope of authorisation and dosage forms WAVE PHARMA LIMITED, GROUND FLOOR, CAVENDISH HOUSE, 369 BURNT OAK BROADWAY, EDGWARE, HA8 5AW, UNITED KINGDOM

6: Legal Basis of authorisation ANNEX 1 and/ or ANNEX 2

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

8: Authorisation Date Confidential

9: Annexes attached 13/06/2025

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

WAVE PHARMA LIMITED, GROUND FLOOR, CAVENDISH HOUSE, 369 BURNT OAK BROADWAY, EDGWARE, HA8 5AW, 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

[2.2.1] 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

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

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Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.5] Packaging

[1.5.2] Secondary packaging