Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 42289

WAVE PHARMA LIMITED 2: Name of authorisation holder

WAVE PHARMA LIMITED, GROUND FLOOR, CAVENDISH 3: Address(es) of manufacturing site(s)

HOUSE, 369 BURNT OAK BROADWAY, EDGWARE, HA8 5AW,

UNITED KINGDOM

WAVE PHARMA LIMITED, GROUND FLOOR, CAVENDISH

HOUSE, 369 BURNT OAK BROADWAY, EDGWARE, HA8 5AW

UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI 6: Legal Basis of authorisation

2012/1916)

Confidential

7: Name of responsible officer of the competent authority of

the member state granting the manufacturing authorisation

4: Legally registered address of authorisation holder

8: Authorisation Date 02/12/2024

9: Annexes attached 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

Issue Date: 02 Dec 2024

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

[2.2.3] Biological medicinal products

[2.2.3.5] Biotechnology products

