

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 34799
2: Name of authorisation holder	IPG PHARMA LIMITED
3: Address(es) of manufacturing site(s)	IPG PHARMA LIMITED, VENTURE HOUSE, 2 ARLINGTON SQUARE, DOWNSHIRE WAY, BRACKNELL, RG12 1WA, UNITED KINGDOM
4: Legally registered address of authorisation holder	IPG PHARMA LIMITED, VENTURE HOUSE, 2 ARLINGTON SQUARE, DOWNSHIRE WAY, BRACKNELL, RG12 1WA, 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	13/06/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

IPG PHARMA LIMITED, VENTURE HOUSE, 2 ARLINGTON SQUARE, DOWNSHIRE WAY, BRACKNELL, RG12 1WA, 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 [1.6] Quality control testing [1.6.1] Microbiological: sterility [1.6.2] Microbiological: non-sterility [1.6.3] Chemical/Physical Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

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