

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK No Data Found

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 15/07/2024

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