

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 32301

2: Name of authorisation holder EISAI MANUFACTURING LIMITED

3: Address(es) of manufacturing site(s) EISAI MANUFACTURING LIMITED, EUROPEAN KNOWLEDGE CENTRE, MOSQUITO WAY, HATFIELD, AL10 9SN, UNITED KINGDOM

4: Legally registered address of authorisation holder EISAI MANUFACTURING LIMITED, EUROPEAN KNOWLEDGE CENTRE, MOSQUITO WAY, HATFIELD, AL10 9SN, UNITED KINGDOM

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

6: Legal Basis of authorisation Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Confidential

8: Authorisation Date 16/08/2021

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

EISAI MANUFACTURING LIMITED, EUROPEAN KNOWLEDGE CENTRE, MOSQUITO WAY, HATFIELD, AL10 9SN, UNITED KINGDOM

Human Investigational 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 Investigational Medicinal Products [1.1.3] Batch certification [1.2] Non-sterile investigational medicinal products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.13] Tablets [1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.5] Biotechnology products

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.13] Tablets

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.3] Chemical/Physical

[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