

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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| 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

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| 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