Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

UK MIA 40147

- 1: Authorisation Number
- 2: Name of authorisation holder
- 3: Address(es) of manufacturing site(s)

ENNOGEN PHARMA LIMITED

ENNOGEN HEALTHCARE LIMITED \ ENNOGEN PHARMA LIMITED, UNIT G3, RIVERSIDE INDUSTRIAL ESTATE, RIVERSIDE WAY, DARTFORD, DA1 5BS, UNITED KINGDOM

- 4: Legally registered address of authorisation holder
- 5: Scope of authorisation and dosage forms
- 6: Legal Basis of authorisation

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

- 8: Authorisation Date
- 9: Annexes attached

ENNOGEN PHARMA LIMITED, UNIT G4, RIVERSIDE INDUSTRIAL ESTATE, RIVERSIDE WAY, DARTFORD, DA1 5BS, UNITED KINGDOM ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

Confidential

25/07/2024

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1 Name and address of the site:

ENNOGEN HEALTHCARE LIMITED \ ENNOGEN PHARMA LIMITED, UNIT G3, RIVERSIDE INDUSTRIAL ESTATE, RIVERSIDE WAY, DARTFORD, DA1 5BS, 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 | |
| [2.2.2] Non-sterile products | |
| | |