Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 40147

2: Name of authorisation holder ENNOGEN PHARMA LIMITED

ENNOGEN HEALTHCARE LIMITED \ ENNOGEN PHARMA LIMITED, UNIT

3: Address(es) of manufacturing site(s) G3 & G4, RIVERSIDE INDUSTRIAL ESTATE, RIVERSIDE WAY,

DARTFORD, DA1 5BS, UNITED KINGDOM

4: Legally registered address of authorisation holder

ESTATE, RIVERSIDE WAY, DARTFORD, DA1 5BS, 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 Confidential

manufacturing authorisation

8: Authorisation Date 01/03/2024

9: Annexes attached 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 & G4, 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

Issue Date: 01 Mar 2024