

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 40147
2: Name of authorisation holder	ENNOGEN PHARMA LIMITED
3: Address(es) of manufacturing site(s)	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	ENNOGEN PHARMA LIMITED, UNIT G4, RIVERSIDE INDUSTRIAL 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 manufacturing authorisation	Confidential
8: Authorisation Date	06/02/2025
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, 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