

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 44669
2: Name of authorisation holder	TANNER PHARMA UK LIMITED
3: Address(es) of manufacturing site(s)	TANNER PHARMA UK LIMITED, THE TITHE BARN, HARPENDENBURY FARM, HARPENDENBURY, REDBOURN, ST. ALBANS, AL3 7QA, UNITED KINGDOM
4: Legally registered address of authorisation holder	TANNER PHARMA UK LIMITED, THE TITHE BARN, HARPENDENBURY FARM, HARPENDENBURY, REDBOURN, ST. ALBANS, AL3 7QA, 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	27/04/2023
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

TANNER PHARMA UK LIMITED, THE TITHE BARN, HARPENDENBURY FARM, HARPENDENBURY, REDBOURN, ST. ALBANS, AL3 7QA, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [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 [2.2.3.2] Immunological products

[2.2.3.5] Biotechnology products

[2.3] Other Importation Activities

[2.3.2] Importation of Intermediate which undergoes further processing

[2.3.4] Other

Issuing a GMP statement of compliance for IMPs imported from third country