

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 22/08/2024

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 & Importation of QP certified IMPs from a country on the approved country for import list