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

TANNER PHARMA UK LIMITED, THE TITHE BARN, HARPENDENBURY

3: Address(es) of manufacturing site(s) FARM, HARPENDENBURY, REDBOURN, ST. ALBANS, AL3 7QA,

UNITED KINGDOM

TANNER PHARMA UK LIMITED, THE TITHE BARN, HARPENDENBURY

4: Legally registered address of authorisation holder 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

Issue Date: 27 Apr 2023

[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

