Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 43461

2: Name of authorisation holder FLAMINGO PHARMA (UK) LIMITED

3: Address(es) of manufacturing site(s)

FLAMINGO PHARMA (UK) LIMITED, THE BLOC, 38 SPRINGFIELD

WAY, ANLABY, HULL, HU10 6RJ, UNITED KINGDOM

FLAMINGO PHARMA (UK) LIMITED, 1ST FLOOR, KIRKLAND HOUSE,

4: Legally registered address of authorisation holder 11-15 PETERBOROUGH ROAD, HARROW, HA1 2AX, 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 Confidential

authorisation

8: Authorisation Date 19/11/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

FLAMINGO PHARMA (UK) LIMITED, THE BLOC, 38 SPRINGFIELD WAY, ANLABY, HULL, HU10 6RJ, UNITED KINGDOM

Human 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

[2.2.2] Non-sterile products

Issue Date: 19 Nov 2024