

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 42117
2: Name of authorisation holder	EMCURE PHARMA UK LIMITED
3: Address(es) of manufacturing site(s)	EMCURE PHARMA UK LIMITED, BASEPOINT BUSINESS CENTRE, 110 BUTTERFIELD, GREAT MARLINGS, LUTON, LU2 8DL, UNITED KINGDOM
4: Legally registered address of authorisation holder	EMCURE PHARMA UK LIMITED, 220 BUTTERFIELD, GREAT MARLINGS, LUTON, LU2 8DL, 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	01/11/2023
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

EMCURE PHARMA UK LIMITED, BASEPOINT BUSINESS CENTRE, 110 BUTTERFIELD, GREAT MARLINGS, LUTON, LU2 8DL,
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 [2.2.1] Sterile Products [2.2.1.1] Aseptically prepared [2.2.1.2] Terminally sterilised [2.2.2] Non-sterile products [2.3] Other Importation Activities [2.3.2] Importation of Intermediate which undergoes further processing

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