

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 37349

2: Name of authorisation holder BAP PHARMA LIMITED

3: Address(es) of manufacturing site(s) BAP PHARMA LIMITED, MEDINA HOUSE, GLOBE BUSINESS PARK, FIELDHOUSE LANE, MARLOW, SL7 1TB, UNITED KINGDOM

4: Legally registered address of authorisation holder BAP PHARMA LIMITED, MEDINA HOUSE, GLOBE BUSINESS PARK, FIELDHOUSE LANE, MARLOW, SL7 1TB, 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 21/01/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

BAP PHARMA LIMITED, MEDINA HOUSE, GLOBE BUSINESS PARK, FIELDHOUSE LANE, MARLOW, SL7 1TB, 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 [2.3] Other Importation Activities [2.3.1] Site of Physical Importation [2.3.2] Importation of Intermediate which undergoes further processing

[2.3.3] Biological Active Substance

[2.3.4] Other

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