

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 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 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 05/11/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BAP PHARMA LIMITED, MEDINA HOUSE, GLOBE BUSINESS PARK, FIELDHOUSE LANE, MARLOW, SL7 1TB, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Products [1.1.3] Batch certification [1.2] Non-sterile products [1.2.2] Batch certification [1.5] Packaging [1.5.2] Secondary packaging 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