

# 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<br><b>[ 2.2 ] Batch certification of imported medicinal products</b><br>[ 2.2.1 ] Sterile Products<br>[ 2.2.1.1 ] Aseptically prepared<br>[ 2.2.1.2 ] Terminally sterilised<br>[ 2.2.2 ] Non-sterile products<br><b>[ 2.3 ] Other Importation Activities</b><br>[ 2.3.1 ] Site of Physical Importation<br>[ 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