# 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** | 08/06/2026 |
| **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

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| Human Investigational Medicinal Products |
| Authorised Operations |
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2) |

**Part 1 - MANUFACTURING OPERATIONS**

**[ 1.2 ] Non-sterile investigational medicinal 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

MHRA-GMDP MHRA

[ 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

MHRA-GMDP MHRA-GMDP MHRA-GMDP MHRA-GMDP