# Medicines and Healthcare products Regulatory Agency

### MANUFACTURER'S AUTHORISATION

1: Authorisation Number

UK MIA(IMP) 37349

2: Name of authorisation holder

BAP PHARMA LIMITED

BAP PHARMA LIMITED, MEDINA HOUSE, GLOBE BUSINESS

3: Address(es) of manufacturing site(s)

PARK, FIELDHOUSE LANE, MARLOW, SL7 1TB, UNITED

**KINGDOM** 

BAP PHARMA LIMITED, MEDINA HOUSE, GLOBE BUSINE<mark>SS</mark>

PARK, FIELDHOUSE LANE, MARLOW, SL7 1TB, UNITED

**KINGDOM** 

Confidential

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

4: Legally registered address of authorisation holder

8: Authorisation Date 06/10/2025

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** 

MANUFACTURING OPERATIONS (according to part 1)

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

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- [ 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



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