

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 58117
<b>2: Name of authorisation holder</b>	PINNACLE IMP LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	PINNACLE IMP LIMITED, ADVANCED TECHNOLOGY AND INNOVATION CENTRE, LOUGHBOROUGH UNIVERSITY SCIENCE AND ENTERPRISE PARK, 5 OAKWOOD DRIVE, LOUGHBOROUGH, LE11 3QF, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	PINNACLE IMP LIMITED, ADVANCED TECHNOLOGY AND INNOVATION CENTRE, LOUGHBOROUGH UNIVERSITY SCIENCE AND ENTERPRISE PARK, 5 OAKWOOD DRIVE, LOUGHBOROUGH, LE11 3QF, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	24/09/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**PINNACLE IMP LIMITED**, ADVANCED TECHNOLOGY AND INNOVATION CENTRE, LOUGHBOROUGH UNIVERSITY SCIENCE AND ENTERPRISE PARK, 5 OAKWOOD DRIVE, LOUGHBOROUGH, LE11 3QF, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b>
<b>[ 1.1 ] Sterile Investigational Medicinal Products</b>
[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)
[ 1.1.1.4 ] Small volume liquids
[ 1.1.1.5 ] Solids and implants

[ 1.1.2 ] Terminally Sterilised (processing operations for the following dosage forms)

[ 1.1.2.2 ] Semi-solids

[ 1.1.2.3 ] Small volume liquids

[ 1.1.2.4 ] Solids and implants

[ 1.1.3 ] Batch certification

**[ 1.2 ] Non-sterile investigational medicinal products**

[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)

[ 1.2.1.11 ] Semi-solids

[ 1.2.1.14 ] Transdermal patches

[ 1.2.2 ] Batch certification

**[ 1.5 ] Packaging**

[ 1.5.1 ] Primary packaging

[ 1.5.1.11 ] Semi-solids

[ 1.5.1.14 ] Transdermal patches

**[ 1.6 ] Quality control testing**

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.3 ] Chemical/Physical