

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 58117

2: Name of authorisation holder PINNACLE IMP LIMITED

3: Address(es) of manufacturing site(s) PINNACLE IMP LIMITED, ADVANCED TECHNOLOGY AND INNOVATION CENTRE, LOUGHBOROUGH UNIVERSITY SCIENCE AND ENTERPRISE PARK, 5 OAKWOOD DRIVE, LOUGHBOROUGH, LE11 3QF, UNITED KINGDOM

4: Legally registered address of authorisation holder PINNACLE IMP LIMITED, ADVANCED TECHNOLOGY AND INNOVATION CENTRE, LOUGHBOROUGH UNIVERSITY SCIENCE AND ENTERPRISE PARK, 5 OAKWOOD DRIVE, LOUGHBOROUGH, LE11 3QF, 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 24/09/2024

9: Annexes attached 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

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|---|
| Human Investigational Medicinal Products |
| Authorised Operations |
| MANUFACTURING OPERATIONS (according to part 1) |
| Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Investigational Medicinal Products [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