

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 36904

2: Name of authorisation holder NAPP PHARMACEUTICAL HOLDINGS LIMITED

3: Address(es) of manufacturing site(s) NAPP PHARMACEUTICAL HOLDINGS LIMITED, UNIT 191,
CAMBRIDGE SCIENCE PARK, MILTON ROAD, CAMBRIDGE, CB4
0GW, UNITED KINGDOM

4: Legally registered address of authorisation holder NAPP PHARMACEUTICAL HOLDINGS LIMITED, UNIT 191,
CAMBRIDGE SCIENCE PARK, MILTON ROAD, CAMBRIDGE, CB4
0GW, UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

6: Legal Basis of authorisation Regulation 17 of The Human Medicines Regulations 2012 (SI
2012/1916)

**7: Name of responsible officer of the competent authority
of the member state granting the manufacturing
authorisation** Confidential

8: Authorisation Date 15/04/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

**NAPP PHARMACEUTICAL HOLDINGS LIMITED, UNIT 191, CAMBRIDGE SCIENCE PARK, MILTON ROAD, CAMBRIDGE, CB4
0GW, UNITED KINGDOM**

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| Human Medicinal Products |
| Authorised Operations |
| IMPORTATION OF MEDICINAL PRODUCTS (according to part 2) |
| Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [2.1] Quality control testing of imported medicinal products [2.1.3] Chemical/Physical [2.2] Batch certification of imported medicinal products [2.2.1] Sterile Products [2.2.1.1] Aseptically prepared [2.2.1.2] Terminally sterilised |

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