

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

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|---|---|
| <b>1: Authorisation Number</b>  | UK MIA 36904  |
| <b>2: Name of authorisation holder</b>  | NAPP PHARMACEUTICAL HOLDINGS LIMITED  |
| <b>3: Address(es) of manufacturing site(s)</b>  | BARD PHARMACEUTICALS LIMITED, UNIT 191, CAMBRIDGE SCIENCE PARK, MILTON ROAD, CAMBRIDGE, CB4 0GW, UNITED KINGDOM         |
| <b>4: Legally registered address of authorisation holder</b>  | NAPP PHARMACEUTICAL HOLDINGS LIMITED, UNIT 191, CAMBRIDGE SCIENCE PARK, MILTON ROAD, CAMBRIDGE, CB4 0GW, UNITED KINGDOM |
| <b>5: Scope of authorisation and dosage forms</b>   | ANNEX 1 and/ or ANNEX 2   |
| <b>6: Legal Basis of authorisation</b>  | Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)  |
| <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>  | 25/07/2024  |
| <b>9: Annexes attached</b>  | Annex 1 and/or Annex 2  |

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**BARD PHARMACEUTICALS 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<br><b>[ 2.1 ] Quality control testing of imported medicinal products</b><br>[ 2.1.3 ] Chemical/Physical<br><b>[ 2.2 ] Batch certification of imported medicinal products</b><br>[ 2.2.1 ] Sterile Products<br>[ 2.2.1.1 ] Aseptically prepared<br>[ 2.2.1.2 ] Terminally sterilised<br>[ 2.2.2 ] Non-sterile products |