

# 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)	BARD PHARMACEUTICALS 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 198, CAMBRIDGE SCIENCE PARK, MILTON ROAD, CAMBRIDGE, CB4 0AB, 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	01/12/2022
9: Annexes attached	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

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 [ 2.2.2 ] Non-sterile products