

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA 20075

**2: Name of authorisation holder** ACCORD HEALTHCARE LIMITED

**3: Address(es) of manufacturing site(s)** ACCORD HEALTHCARE LIMITED, EDGEFIELD AVENUE, NEWCASTLE UPON TYNE, NE3 3NB, UNITED KINGDOM

**4: Legally registered address of authorisation holder** ACCORD HEALTHCARE LIMITED, GROUND FLOOR, SAGE HOUSE, 319 PINNER ROAD, HARROW, HA1 4HF, 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** 03/07/2025

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**ACCORD HEALTHCARE LIMITED**, EDGEFIELD AVENUE, NEWCASTLE UPON TYNE, NE3 3NB, UNITED KINGDOM

|                                                                                                                                                                                                                                   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Human Medicinal Products                                                                                                                                                                                                          |
| Authorised Operations                                                                                                                                                                                                             |
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)                                                                                                                         |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.2 ] Non-sterile products</b><br>[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)<br>[ 1.2.1.13 ] Tablets<br>[ 1.2.2 ] Batch certification |

**[ 1.5 ] Packaging**

- [ 1.5.1 ] Primary packaging
  - [ 1.5.1.1 ] Capsules, hard shell
  - [ 1.5.1.13 ] Tablets
- [ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

- [ 1.6.1 ] Microbiological: sterility
- [ 1.6.2 ] Microbiological: non-sterility
- [ 1.6.3 ] Chemical/Physical
- [ 1.6.4 ] Biological

**Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**

**[ 2.1 ] Quality control testing of imported medicinal products**

- [ 2.1.1 ] Microbiological: sterility
- [ 2.1.2 ] Microbiological: non-sterility
- [ 2.1.3 ] Chemical/Physical
- [ 2.1.4 ] Biological

**[ 2.2 ] Batch certification of imported medicinal products**

- [ 2.2.2 ] Non-sterile products

**[ 2.3 ] Other Importation Activities**

- [ 2.3.2 ] Importation of Intermediate which undergoes further processing

**SCOPE OF AUTHORISATION**

**Annex 1**

Name and address of the site:

**ACCORD HEALTHCARE LIMITED**, GROUND FLOOR, SAGE HOUSE, 319 PINNER ROAD, HARROW, HA1 4HF, UNITED KINGDOM

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
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| Human Medicinal Products                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Authorised Operations                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Products</b> <ul style="list-style-type: none"><li>[ 1.1.3 ] Batch certification</li></ul> <b>[ 1.2 ] Non-sterile products</b> <ul style="list-style-type: none"><li>[ 1.2.2 ] Batch certification</li></ul> <b>[ 1.3 ] Biological medicinal products</b> <ul style="list-style-type: none"><li>[ 1.3.2 ] Batch certification</li><li>[ 1.3.2.5 ] Biotechnology products</li></ul> <b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b><br><b>[ 2.2 ] Batch certification of imported medicinal products</b> <ul style="list-style-type: none"><li>[ 2.2.1 ] Sterile Products</li></ul> |

[ 2.2.1.1 ] Aseptically prepared

[ 2.2.1.2 ] Terminally sterilised

[ 2.2.2 ] Non-sterile products

[ 2.2.3 ] Biological medicinal products

[ 2.2.3.5 ] Biotechnology products

**[ 2.3 ] Other Importation Activities**

[ 2.3.2 ] Importation of Intermediate which undergoes further processing