Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

UK MIA 20075 1: Authorisation Number

2: Name of authorisation holder ACCORD HEALTHCARE LIMITED

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

KINGDOM

ACCORD HEALTHCARE LIMITED, EDGEFIELD AVENUE,

NEWCASTLE UPON TYNE, NE3 3NB, UNITED KINGDOM

ACCORD HEALTHCARE LIMITED, GROUND FLOOR, SAGE

4: Legally registered address of authorisation holder HOUSE, 319 PINNER ROAD, HARROW, HA1 4HF, UNITED

KINGDOM

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

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

2012/1916)

Confidential

7: Name of responsible officer of the competent authority of the

member state granting the manufacturing authorisation

21/10/2025 8: Authorisation Date

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

3: Address(es) of manufacturing site(s)

Annex 1

Name and address of the site:

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

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Products

[1.1.3] Batch certification

[1.2] Non-sterile products

[1.2.2] Batch certification

Issue Date: 21 Oct 2025

[1.3] Biological medicinal products [1.3.2] Batch certification [1.3.2.5] Biotechnology products Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [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 [2.2.3] Biological medicinal products [2.2.3.5] Biotechnology products [2.3.1] 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, EDGEFIELD AVENUE, NEWCASTLE UPON TYNE, NE3 3NB, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.13] Tablets

[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

Issue Date: 21 Oct 2025

- [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



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