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, GROUND FLOOR, SAGE HOUSE, 319 PINNER ROAD, HARROW, HA1 4HF, UNITED KINGDOM 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	28/01/2026
9: Annexes attached	Annex 1 and/or Annex 2

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

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

[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] 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

[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