

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 8731

2: Name of authorisation holder FERRING CONTROLLED THERAPEUTICS LIMITED

3: Address(es) of manufacturing site(s) FERRING CONTROLLED THERAPEUTICS LIMITED, 1 REDWOOD PLACE, PEEL PARK CAMPUS, EAST KILBRIDE, GLASGOW, G74 5PB, UNITED KINGDOM

4: Legally registered address of authorisation holder FERRING CONTROLLED THERAPEUTICS LIMITED, 12 REDWOOD CRESCENT, PEEL PARK CAMPUS, EAST KILBRIDE, GLASGOW, G74 5PA, 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 09/09/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

FERRING CONTROLLED THERAPEUTICS LIMITED, 1 REDWOOD PLACE, PEEL PARK CAMPUS, EAST KILBRIDE, GLASGOW, G74 5PB, 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

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

[1.2.1.8] Other solid dosage forms

[1.2.2] Batch certification

[1.3] Biological medicinal products

[1.3.2] Batch certification

[1.3.2.5] Biotechnology products

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.11] Semi-solids

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[1.1] Sterile Products

[1.1.3] Batch certification

[1.2] Non-sterile products

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

[1.2.1.8] Other solid dosage forms

[1.2.2] Batch certification

[1.3] Biological medicinal products

[1.3.2] Batch certification

[1.3.2.5] Biotechnology products

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.11] Semi-solids

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[2.3] Other Importation Activities

[2.3.4] Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)

Secondary packaging only

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

FERRING CONTROLLED THERAPEUTICS LIMITED, 12 REDWOOD CRESCENT, PEEL PARK CAMPUS, EAST KILBRIDE,
GLASGOW, G74 5PA, 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 [1.5] Packaging [1.5.2] Secondary packaging [1.6] Quality control testing [1.6.3] Chemical/Physical Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [2.2] Batch certification of imported medicinal products [2.2.3] Biological medicinal products [2.2.3.5] Biotechnology products