

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 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 Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Confidential

8: Authorisation Date 01/11/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

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

Human Investigational 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 investigational medicinal products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.8] Other solid dosage forms

[1.5] Packaging

[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

[1.2] Non-sterile investigational medicinal products

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

[1.2.1.8] Other solid dosage forms

[1.5] Packaging

[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] Other

Importation for Secondary Packaging

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

FERRING CONTROLLED THERAPEUTICS LIMITED, 12 REDWOOD CRESCENT, PEEL PARK CAMPUS, EAST KILBRIDE,
GLASGOW, G74 5PA, UNITED KINGDOM

Human Investigational 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