

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, 1 REDWOOD PLACE, PEEL PARK CAMPUS, EAST KILBRIDE, GLASGOW, G74 5PB, 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	17/11/2022
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