

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number

UK MIA(IMP) 29595

2: Name of authorisation holder

PIRAMAL HEALTHCARE UK LIMITED

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

PIRAMAL HEALTHCARE UK LIMITED, 2 ROSELAND HALL,
EARLS GATE PARK, GRANGEMOUTH, FK3 8ZF, UNITED
KINGDOM

4: Legally registered address of authorisation holder

PIRAMAL HEALTHCARE UK LIMITED , WHALTON ROAD,
MORPETH, NORTHUMBERLAND, NE61 3YA, UNITED
KINGDOM

5: Scope of authorisation and dosage forms

PIRAMAL HEALTHCARE UK LIMITED, EARLS ROAD,
GRANGEMOUTH, FK3 8XG, UNITED KINGDOM

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

17/12/2025

9: Annexes attached

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

PIRAMAL HEALTHCARE UK LIMITED, 2 ROSELAND HALL, EARLS GATE PARK, GRANGEMOUTH, FK3 8ZF, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile investigational medicinal products

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

- [1.2.1.15] Other non-sterile medicinal products
 - Liquid conjugate bulk drug substances in solution

Special Requirements

- Including cytotoxic and potent bulk drug substances

- [1.2.2] Batch certification

[1.3] Biological investigational medicinal products

- [1.3.1] Biological medicinal products

- [1.3.1.8] Other biological medicinal products

QP batch certification of the manufacturing and testing conducted on liquid conjugate bulk drug substances in solution

Special Requirements

- Including cytotoxic and potent bulk drug substances

[1.6] Quality control testing

- [1.6.2] Microbiological: non-sterility

- [1.6.3] Chemical/Physical

- [1.6.4] Biological

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

PIRAMAL HEALTHCARE UK LIMITED , WHALTON ROAD, MORPETH, NORTHUMBERLAND, NE61 3YA, 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)

- [1.2.1.1] Capsules, hard shell

- [1.2.1.13] Tablets

Special Requirements

Range of hormonal property tablets

- [1.2.1.15] Other non-sterile medicinal products

Tablet/ medical device combination. Over encapsulation of a rangedosage forms

- [1.2.2] Batch certification

[1.3] Biological investigational medicinal products

- [1.3.2] Batch certification

- [1.3.2.5] Biotechnology products

[1.5] Packaging

- [1.5.1] Primary packaging

- [1.5.1.1] Capsules, hard shell

- [1.5.1.13] Tablets

- [1.5.1.15] Other non-sterile medicinal products
 - Packaging of a range of over encapsulated range of products. Packaging of tablet/ medical device combination
- [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

[2.1] Quality control testing of imported medicinal products

- [2.1.2] Microbiological: non-sterility
- [2.1.3] Chemical/Physical

[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

- [2.3.1] Site of Physical Importation
- [2.3.2] Importation of Intermediate which undergoes further processing
- [2.3.4] Other
 - Batch Certification of products imported into EU but not to the Piramal Morpeth site

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

PIRAMAL HEALTHCARE UK LIMITED, EARLS ROAD, GRANGEMOUTH, FK3 8XG, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile investigational medicinal products

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

- [1.2.1.15] Other non-sterile medicinal products

Liquid conjugate bulk drug substances in solution

Special Requirements

Including cytotoxic and potent bulk drug substances

- [1.2.2] Batch certification

[1.3] Biological investigational medicinal products

- [1.3.1] Biological medicinal products

[1.3.1.8] Other biological medicinal products

QP certification of the manufacturing and testing conducted on Liquid conjugate bulk drug substances in solution

Special Requirements

Including cytotoxic and potent bulk drug substances

[1.3.2] Batch certification

[1.3.2.8] Other biological medicinal products

QP certification of the manufacturing and testing conducted on Liquid conjugate bulk drug substances in solution

Special Requirements

Including cytotoxic and potent bulk drug substances

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological