

# 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