

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 29595
<b>2: Name of authorisation holder</b>	PIRAMAL HEALTHCARE UK LIMITED PIRAMAL HEALTHCARE UK LIMITED, 2 ROSELAND HALL, EARLS GATE PARK, GRANGEMOUTH, FK3 8ZF, UNITED KINGDOM
<b>3: Address(es) of manufacturing site(s)</b>	PIRAMAL HEALTHCARE UK LIMITED , WHALTON ROAD, MORPETH, NORTHUMBERLAND, NE61 3YA, UNITED KINGDOM  PIRAMAL HEALTHCARE UK LIMITED, EARLS ROAD, GRANGEMOUTH, FK3 8XG, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	PIRAMAL HEALTHCARE UK LIMITED, WHALTON ROAD, MORPETH, NORTHUMBERLAND, NE61 3YA, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	21/11/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

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

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.2 ] Non-sterile products</b> [ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)

- [ 1.2.1.17 ] 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 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 1**

Name and address of the site:

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

Human Medicinal Products
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Authorised Operations
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MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
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<p><b>Part 1 - MANUFACTURING OPERATIONS</b></p> <p><b>[ 1.1 ] Sterile Products</b></p> <ul style="list-style-type: none"> <li>[ 1.1.2 ] Terminally Sterilised (processing operations for the following dosage forms)           <ul style="list-style-type: none"> <li>[ 1.1.2.5 ] Other terminally sterilised prepared products               <ul style="list-style-type: none"> <li>Secondary Packaging and Batch Certification of terminally sterilised ampoules</li> </ul> </li> </ul> </li> <li>[ 1.1.3 ] Batch certification</li> </ul> <p><b>[ 1.2 ] Non-sterile products</b></p> <ul style="list-style-type: none"> <li>[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)           <ul style="list-style-type: none"> <li>[ 1.2.1.1 ] Capsules, hard shell</li> <li>[ 1.2.1.8 ] Other solid dosage forms               <ul style="list-style-type: none"> <li><b>Special Requirements</b></li> <li>Granules with hormonal properties</li> </ul> </li> <li>[ 1.2.1.13 ] Tablets               <ul style="list-style-type: none"> <li><b>Special Requirements</b></li> <li>Range of hormonal/ hormonal property tablets</li> </ul> </li> </ul> </li> <li>[ 1.2.2 ] Batch certification</li> </ul> <p><b>[ 1.5 ] Packaging</b></p>
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- [ 1.5.1 ] Primary packaging
  - [ 1.5.1.1 ] Capsules, hard shell
  - [ 1.5.1.2 ] Capsules, soft shell
  - [ 1.5.1.8 ] Other solid dosage forms
- Special Requirements**
- Granules with hormonal properties
- [ 1.5.1.13 ] Tablets

**Special Requirements**

Range of hormonal/ hormonal property tablets

- [ 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

**[ 2.3 ] Other Importation Activities**

- [ 2.3.1 ] Site of Physical Importation
- [ 2.3.2 ] Importation of Intermediate which undergoes further processing

**SCOPE OF AUTHORISATION**

**Annex 1**

Name and address of the site:

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

Human Medicinal Products
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Authorised Operations
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MANUFACTURING OPERATIONS (according to part 1)
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**Part 1 - MANUFACTURING OPERATIONS**

**[ 1.2 ] Non-sterile products**

- [ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)
  - [ 1.2.1.17 ] 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 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