

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 29595
<b>2: Name of authorisation holder</b>	PIRAMAL HEALTHCARE UK LIMITED PIRAMAL HEALTHCARE UK LIMITED, EARLS ROAD, GRANGEMOUTH, FK3 8XG, UNITED KINGDOM PIRAMAL HEALTHCARE UK LIMITED , WHALTON ROAD, MORPETH, NORTHUMBERLAND, NE61 3YA, UNITED KINGDOM 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
<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>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<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 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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.2 ] Non-sterile investigational medicinal products</b> [ 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

**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)
<p><b>Part 1 - MANUFACTURING OPERATIONS</b></p> <p><b>[ 1.2 ] Non-sterile investigational medicinal 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>[ 1.2.1.13 ] Tablets</li> </ul> </li> </ul> <p><b>Special Requirements</b></p> <ul style="list-style-type: none"> <li>Range of hormonal property tablets</li> <li>[ 1.2.1.15 ] Other non-sterile medicinal products           <ul style="list-style-type: none"> <li>Tablet/ medical device combination. Over encapsulation of a ranged dosage forms</li> </ul> </li> </ul> <p>[ 1.2.2 ] Batch certification</p> <p><b>[ 1.3 ] Biological investigational medicinal products</b></p> <ul style="list-style-type: none"> <li>[ 1.3.2 ] Batch certification</li> </ul>

[ 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, 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