

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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| 1: Authorisation Number | UK MIA(IMP) 29595 |
| 2: Name of authorisation holder | PIRAMAL HEALTHCARE UK LIMITED PIRAMAL HEALTHCARE UK LIMITED, EARLS ROAD, GRANGEMOUTH, FK3 8XG, UNITED KINGDOM PIRAMAL HEALTHCARE UK LIMITED, 2 ROSELAND HALL, EARLS GATE PARK, GRANGEMOUTH, FK3 8ZF, UNITED KINGDOM |
| 3: Address(es) of manufacturing site(s) | PIRAMAL HEALTHCARE UK LIMITED , WHALTON ROAD, MORPETH, NORTHUMBERLAND, NE61 3YA, UNITED KINGDOM PIRAMAL HEALTHCARE UK LIMITED, WHALTON ROAD, MORPETH, NORTHUMBERLAND, NE61 3YA, 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 | 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 | 10/06/2026 |
| 9: Annexes attached | 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

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| 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

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

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

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| <p>Part 1 - MANUFACTURING OPERATIONS</p> <p>[1.2] Non-sterile investigational medicinal products</p> <ul style="list-style-type: none"> [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) <ul style="list-style-type: none"> [1.2.1.15] Other non-sterile medicinal products <ul style="list-style-type: none"> Liquid conjugate bulk drug substances in solution Special Requirements Including cytotoxic and potent bulk drug substances [1.2.2] Batch certification <p>[1.3] Biological investigational medicinal products</p> <ul style="list-style-type: none"> [1.3.1] Biological medicinal products |
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[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 ranged dosage 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