Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 29595
2: Name of authorisation holder	PIRAMAL HEALTHCARE UK LIMITED
3: Address(es) of manufacturing site(s)	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 PIRAMAL HEALTHCARE UK LIMITED, EARLS ROAD, GRANGEMOUTH, FK3 8XG, 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	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
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 1

Name and address of the site:

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

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Products

MHRA-GMDP

[1.1.2] Terminally Sterilised (processing operations for the following dosage forms)

[1.1.2.5] Other terminally sterilised prepared products

Secondary Packaging and Batch Certification of terminally sterilised ampoules

[1.1.3] Batch certification

[1.2] Non-sterile products

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

[1.2.1.1] Capsules, hard shell

[1.2.1.8] Other solid dosage forms

Special Requirements

Granules with hormonal properties

[1.2.1.13] Tablets

Special Requirements

Range of hormonal/ hormonal property tablets

[1.2.2] Batch certification

[1.5] Packaging

[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:

MHRA-GMDP MHRA

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)

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 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, EARLS ROAD, GRANGEMOUTH, FK3 8XG, UNITED KINGDOM

Human Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

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

MHRA-GMDP MHRA

[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

MHRA-GMDP MHRA MHRA-GMDP MHRA