

Medicines and Healthcare products Regulatory Agency

REGISTRATION OF MANUFACTURER, IMPORTER OR DISTRIBUTOR OF ACTIVE SUBSTANCES TO BE USED AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

Registrant Details

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| 1. Registration Number | UK API 37071 |
| 2. Name or corporate name of registrant | PIRAMAL CRITICAL CARE LIMITED |
| 3. Permanent or legal address of registrant | PIRAMAL CRITICAL CARE LIMITED, SUITE 4, GROUND FLOOR, HEATHROW BOULEVARD, EAST WING, 280 BATH ROAD, WEST DRAYTON, UB7 0DQ, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | PIRAMAL CRITICAL CARE LIMITED, SUITE 4, GROUND FLOOR, HEATHROW BOULEVARD, EAST WING, 280 BATH ROAD, WEST DRAYTON, UB7 0DQ, UNITED KINGDOM |
| 5. National legal basis of registration | Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916) |
| 6. Name of responsible officer of the competent authority of the member state validating the registration | Confidential |
| 7. Date | 24/02/2026 |

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in MHRA-GMDP.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

SCOPE OF REGISTRATION

Name and address of the site

PIRAMAL CRITICAL CARE LIMITED, SUITE 4, GROUND FLOOR, HEATHROW BOULEVARD, EAST WING, 280 BATH ROAD, WEST DRAYTON, UB7 0DQ, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance 3rd Country Manufacturer

3rd Country
Distributor

ETOMIDATE (1000002879)	PISGAH LABORATORIES , 3222 OLD HENDERSONVILLE HIGHWAY, PISGAH FOREST, 28768, UNITED STATES
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APOTHECON PHARMACEUTICALS PVT LTD., PLOT NO. 1134, 1135, 1136, 1137, 1138-A & B, 1143-B, 1144-A&B, PADRA JAMBUSAR HIGHWAY, DABHASA, PADRA, VADODARA, GUJARAT, IN-391440, INDIA

MIGLUSTAT
(1000000278)

APICORE PHARMACEUTICALS PRIVATE LIMITED, BLOCK NO. 252-253, DHOBHIKUVA VILLAGE, PADRA-JAMBUSAR HIGHWAY, TALUKA PADRA, VADODARA, GUJARAT, IN-391 440, INDIA

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

PIRITRAMIDE (1000009857)

SUFENTANIL CITRATE (2000006818)

ETOMIDATE (1000002879)

ALFENTANIL HYDROCHLORIDE (2000008540)

FENTANYL CITRATE (2000007584)

MIGLUSTAT (1000000278)