

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

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	22/04/2022

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**

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
- ALFENTANIL HYDROCHLORIDE (2000008540)
 - ETOMIDATE (1000002879)
 - SUFENTANIL CITRATE (2000006818)
 - FENTANYL CITRATE (2000007584)
 - PIRITRAMIDE (1000009857)
 - MIGLUSTAT (1000000278)