

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 14023 |
| 2. Name or corporate name of registrant | CATALENT UK SWINDON ZYDIS LIMITED |
| 3. Permanent or legal address of registrant | CATALENT UK SWINDON ZYDIS LIMITED, FRANKLAND ROAD, BLAGROVE, SWINDON, SN5 8RU, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | CATALENT UK SWINDON ZYDIS LIMITED, FRANKLAND ROAD, BLAGROVE, SWINDON, SN5 8RU, 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 | 29/09/2023 |

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

CATALENT UK SWINDON ZYDIS LIMITED, FRANKLAND ROAD, BLAGROVE, SWINDON, SN5 8RU, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance

MIDAZOLAM (1000000928)

3rd Country Manufacturer

WAVELENGTH ENTERPRISES LIMITED, NEOT-HOVAV ECO INDUSTRIAL PARK, BEER SHEVA, IL-8413502, ISRAEL

3rd Country Distributor

RIZATRIPTAN BENZOATE
(2000007163)

AUROBINDO PHARMA LIMITED, UNIT XI, SURVEY NOS. 61-66,
INDUSTRIAL DEVELOPMENT AREA, PYDIBHIMAVARAM, RANASTHALAM
MANDAL, SRIKAKULAM DISTRICT, ANDHRA PRADESH, IN-532409, INDIA

ONDANSETRON
(1000009100)

GLAXO WELLCOME MANUFACTURING PTE LIMITED, 1 PIONEER SECTOR
1, JURONG, SINGAPORE, SG-628413, SINGAPORE

SCOPOLAMINE
HYDROBROMIDE
(4000007162)

ALPS PHARMACEUTICAL INDUSTRIES COMPANY LIMITED, 10-50
FURUKAWACHO MUKAIMACHI NICHOME, HIDA, GIFU, JP-509 4241, JAPAN

ZAVEGEPANT (3000022349)

ANTHEM BIOSCIENCES PVT LIMITED, NO 49, F1 & F2 CANARA BANK
ROAD, BOMMASANDRA INDUSTRIAL AREA, PHASE 1, HOSUR ROAD,
BENGALURU, KARNATAKA, IN-560 099, INDIA

ARIPIPRAZOLE (1000000123)

OTSUKA PHARMACEUTICAL COMPANY LIMITED, 224-18, HIRASHI
EBISUNO, KAWAUCHI-CHO, TOKUSHIMA, JP-771-0182, JAPAN

LORATADINE
HYDROCHLORIDE
(2000017674)

MYLAN LABORATORIES LIMITED, UNIT 7, PLOT NO. 14, 99 & 100 IDA,
PASHAMYLARAM, PHASE II, MEDAK DISTRICT, HYDERABAD, TELANGANA,
IN-502307, INDIA

CRYPTOMERIA JAPONICA
(2000018035)

KNC LABORATORIES COMPANY LIMITED, KNC BIO-RESEARCH CENTER,
1-1-1 MUROTANI, NISHI-KU, KOBE, HYOGO, JP 651-2241, JAPAN

LOPERAMIDE
HYDROCHLORIDE
(2000008494)

VASUDHA PHARMA CHEM LIMITED, UNIT-II, PLOT NO. 79, JAWAHARLAL
NEHRU PHARMA CITY, THANAM, PARAWADA, ANAKAPALLI, ANDHRA
PRADESH, IN-531019, INDIA

RIMEGEPANT (3000020812)

ANTHEM BIOSCIENCES PVT LIMITED, NO 49, F1 & F2 CANARA BANK
ROAD, BOMMASANDRA INDUSTRIAL AREA, PHASE 1, HOSUR ROAD,
BENGALURU, KARNATAKA, IN-560 099, INDIA

IBUPROFEN (1000008918)

IOL CHEMICALS AND PHARMACEUTICALS LIMITED, MANSA ROAD
(TRIDENT COMPLEX), DISTRICT BARNALA, FATEHGARH CHANNA
VILLAGE, PUNJAB, IN-148101, INDIA

CHLORPHENIRAMINE
MALEATE (2000008095)

KONGO CHEMICAL COMPANY LIMITED, NO 3 HIMATA, TOYAMA CITY,
TOYAMA, JP 930-0912, JAPAN

DOMPERIDONE
(1000002907)

VASUDHA PHARMA CHEM LIMITED, UNIT-II, PLOT NO. 79, JAWAHARLAL
NEHRU PHARMA CITY, THANAM, PARAWADA, ANAKAPALLI, ANDHRA
PRADESH, IN-531019, INDIA