

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 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	09/10/2024

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

ARIPIPIRAZOLE
(1000000123)

3rd Country Manufacturer

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

OTSUKA SAGA FACTORY, 5006-5, AZAHIGASHIYAMA, OMAGARI, KANZAKI-
GUN, YOSHINO GARI-CHO, SAGA, JP-842-0197, JAPAN

3rd Country Distributor

LOPERAMIDE
HYDROCHLORIDE
(2000008494)

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

SCOPOLAMINE
HYDROBROMIDE
(4000007162)

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

LORATADINE
HYDROCHLORIDE
(2000017674)

MYLAN LABORATORIES LIMITED, (UNIT 7), PLOT NO. 14, 99 & 100, I.D.A,
PASHAMYLARAM PHASE II, Data Not Available, PATANCHERU, TELANGANA,
IN-502 307, INDIA

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

ANTHEM BIOSCIENCES PVT LIMITED, UNIT II NO. 276-P AND 277-P, 20
BANNIKUPPE ROAD, HAROHALLI INDUSTRIAL AREA PHASE II, KANAKPURA
TALUK, RAMANAGARA, KARNATAKA, IN-562112, INDIA

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

RIMEGEPANT (3000020812)

ESCIENTIA ADVANCED SCIENCES PRIVATE LIMITED, PLOT NO. 11, 11A, 12
AND 12A, APSEZ ATCHUTAPURAM, ANAKAPALLI DISTRICT,
VISAKHAPATNAM, ANDHRA PRADESH, IN-531011, INDIA

PIRAMAL PHARMA LIMITED, SURVEY NOS. 7-70, 70/1 AND 70/2, DIGWAL
VILLAGE, KOHIR MANDAL, KOHIR CROSS ROAD, SANGAREDDY DISTRICT,
TELANGANA, IN-502 321, INDIA

OLANZAPINE (1000007944)

LONZA MONTEGGIO, VIA CANTONALE 4, MONTEGGIO, CH-6998,
SWITZERLAND

CRYPTOMERIA JAPONICA
(2000018035)

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

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

DOMPERIDONE
(1000002907)

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

ONDANSETRON
(1000009100)

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

CHLORPHENIRAMINE
MALEATE (2000008095)

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

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution
 RIMEGEPANT (3000020812)