

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	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
ARIPIPIRAZOLE (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