

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 49402 |
| 2. Name or corporate name of registrant | AZELIS UK LIMITED |
| 3. Permanent or legal address of registrant | AZELIS UK LIMITED, AXIS HOUSE, TUDOR ROAD, MANOR PARK,
RUNCORN, WA7 1BD, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | AZELIS UK LIMITED, FOXHOLES BUSINESS PARK, JOHN TATE
ROAD, HERTFORD, SG13 7YH, 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 | 22/01/2026 |

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

AZELIS UK LIMITED, FOXHOLES BUSINESS PARK, JOHN TATE ROAD, HERTFORD, SG13 7YH, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
PERINDOPRIL ERBUMINE (2000008381)	GLENMARK , PLOT NO. 3109- C, GIDC INDUSTRIAL ESTATE, ANKLESHWAR, DIST. BHARUCH, GUJARAT STATE, IN-393 002, INDIA	
EPHEDRINE HYDROCHLORIDE (2000007671)	EMBio LIMITED , 501 SENTINEL, HIRANANDANI GARDENS, POWAI, MUMBAI, IN-400 076, INDIA	

PSEUDOEPHEDRINE HYDROCHLORIDE (2000007829)	EMBIO LIMITED , 501 SENTINEL, HIRANANDANI GARDENS, POWAI, MUMBAI, IN-400 076, INDIA
MAGALDRATE (1000001270)	SPI PHARMA, INC , 503 CARR ROAD, WILMINGTON, 19809, UNITED STATES
CAPTOPRIL (1000006787)	ZHEJIANG HUAHAI PHARMACEUTICAL CO LIMITED , XUNQIAO, LINHAI CITY, ZHEJIANG PROVINCE, CN-317024, CHINA
INDAPAMIDE (1000008739)	SUZHOU LIXIN PHARMACEUTICAL CO., LIMITED. , 21 TANGXI ROAD, SUZHOU NEW DISTRICT, SUZHOU, CN-215151, CHINA
NOSCAPINE (1000009663)	ALKALOIDS CORPORATION , 8 BENTINCK STREET, KOLKATA, IN-700 001, INDIA
BENZYL NICOTINATE (1000009481)	HERBERT BROWN PHARMACEUTICAL AND RESEARCH LABORATORIES , W-256-A, MIDC PHASE II, SHIVAJI UDYOG NAGAR, DOMBIVLI, THANE, IN-421203, INDIA
MOMETASONE FUROATE (2000008125)	AURISCO PHARMACEUTICAL LIMITED , ROOM 1709-1710 HITECH PLAZA, NO 488 S WU NING ROAD, SHANGHAI, CN-200 042, CHINA
GRANISETRON (1000009464)	CIPLA LIMITED , MANUFACTURING & RESEARCH DIVISION, OLD MADRAS ROAD, VIRGONAGAR DISTRICT, BANGALORE, KARNATAKA, IN-560 049, INDIA
PARACETAMOL (1000009609)	NOVACYL (WUXI) PHARMACEUTICAL COMPANY LIMITED , 16 GUANGSHI ROAD, MEIJING VILLAGE, LUOSHE TOWN, HUIZHAN DISTRICT, WUXI, JIANGSU PROVINCE, CN-214185, CHINA ANQIU LU'AN PHARMACEUTICAL COMPANY LIMITED , 35 WEIXU NORTH ROAD, XIAN STREET, ANQIU CITY, WEIFANG CITY, SHANDONG PROVINCE, CN-262 199, CHINA
CLOPIDOGREL BESILATE (2000013668)	CADILA HEALTHCARE LIMITED , ZYDUS TOWER, 5TH FLOOR- SATELLITE CROSS ROADS, SARKHEJ ROAD, GANDHINAGAR, GUJARAT, IN-380015, INDIA
SODIUM BICARBONATE (1000009540)	SOLVAY PEROXYTHAI LIMITED , NO. 1, 1-3A, MAP TA PHUT INDUSTRIAL ESTATE, TAMBOL MAP TA PHUT, AMPHUR MUANG, RAYONG, TH- 21150, THAILAND

IBUPROFEN (1000008918)

SI GROUP, 725 CANNON BRIDGE ROAD, ORANGEBURG, 29115, UNITED STATES

ENALAPRIL MALEATE
(2000007672)

ZHEJIANG HUAHAI PHARMACEUTICAL CO LIMITED, XUNQIAO, LINHAI CITY, ZHEJIANG PROVINCE, CN-317024, CHINA

ALUMINIUM HYDROXIDE
(1000013126)

SPI PHARMA, INC, 503 CARR ROAD, WILMINGTON, 19809, UNITED STATES

PHENYLEPHRINE
HYDROCHLORIDE
(2000008067)

DIVI'S LABORATORIES LIMITED, DIVI TOWERS 7-1-77/E/1/303 DHARAM KARAN ROAD, AMEERPET, HYDERABAD, TELANGANA, IN-500 016, INDIA

PHENOBARBITAL (1000014071)

NANTONG JINGHUA PHARMACEUTICAL COMPANY LIMITED, 9 XINGTAI ROAD, ZONE GANGZHA, ECONOMIC DEVELOPMENT, NANTONG, JIANGSU, CN-226005, CHINA

PHENYLBUTAZONE
(1000009893)

NANTONG JINGHUA PHARMACEUTICAL COMPANY LIMITED, 43 YAOGANG ROAD, NANTONG, JIANGSU PROVINCE, CN-226 006, CHINA

LISINOPRIL DIHYDRATE
(2000008500)

ZHEJIANG HUAHAI PHARMACEUTICAL CO LIMITED, XUNQIAO, LINHAI CITY, ZHEJIANG PROVINCE, CN-317024, CHINA

MAGNESIUM HYDROXIDE
(1000000894)

SPI PHARMA, INC, 503 CARR ROAD, WILMINGTON, 19809, UNITED STATES

PHENOBARBITONE
(3000014222)

NANTONG JINGHUA PHARMACEUTICAL COMPANY LIMITED, 9 XINGTAI ROAD, ZONE GANGZHA, ECONOMIC DEVELOPMENT, NANTONG, JIANGSU, CN-226005, CHINA

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B

Distribution

METHYL SALICYLATE (1000000149)

CHLORHEXIDINE DIACETATE (4000007351)

DOXYLAMINE SUCCINATE (2000007681)

BENZALKONIUM CHLORIDE (2000010983)

CETRIMIDE (1000006286)

CHLORHEXIDINE GLUCONATE SOLUTION 20% (4000003482)

INDAPAMIDE (1000008739)

SALICYLIC ACID (1000009710)

UREA (1000009262)

PROCAINE HYDROCHLORIDE (2000007906)

NYSTATIN (1000009661)

CARVEDILOL (1000003761)
ASPIRIN (1000009870)
DIAZEPAM (1000003208)
CHLORDIAZEPOXIDE HYDROCHLORIDE (2000008104)
ICHTHAMMOL (1000008905)
LOPERAMIDE HYDROCHLORIDE (2000008494)
PENICILLIN V POTASSIUM (4000007429)
SODIUM CHLORIDE (1000009536)
CHLORHEXIDINE DIHYDROCHLORIDE (4000002466)
CODEINE PHOSPHATE HEMIHYDRATE (4000006570)
LOFEPRAMINE HYDROCHLORIDE (2000008496)
AMANTADINE SULPHATE (2000019040)
PENICILLIN V CALCIUM (4000014135)
SIMETHICONE (1000009128)
BISOPROLOL FUMARATE (2000008290)
LORAZEPAM (1000008543)
MEBEVERINE (1000000255)
DIMETHICONE (3000011022)
POLYMYXIN B SULPHATE (4000010173)
APIXABAN (1000011644)
EPINEPHRINE (1000009945)