

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 | 25/04/2025 |

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
PHENYLBUTAZONE (1000009893)	NANTONG JINGHUA PHARMACEUTICAL COMPANY LIMITED , 43 YAOGANG ROAD, NANTONG, JIANGSU PROVINCE, CN-226 006, 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

CLOPIDOGREL BESILATE
(2000013668)

CADILA HEALTHCARE LIMITED, ZYDUS TOWER, 5TH FLOOR-
SATELLITE CROSS ROADS, SARKHEJ ROAD, GANDHINAGAR,
GUJARAT, IN-380015, INDIA

GRANISETRON (1000009464)

CIPLA LIMITED, MANUFACTURING & RESEARCH DIVISION, OLD
MADRAS ROAD, VIRGONAGAR DISTRICT, BANGALORE, KARNATAKA,
IN-560 049, INDIA

NOSCAPINE (1000009663)

ALKALOIDS CORPORATION, 8 BENTINCK STREET, KOLKATA, IN-700
001, INDIA

MOMETASONE FUROATE
(2000008125)

AURISCO PHARMACEUTICAL LIMITED, ROOM 1709-1710 HITECH
PLAZA, NO 488 S WU NING ROAD, SHANGHAI, CN-200 042, CHINA

ALUMINIUM HYDROXIDE
(1000013126)

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

LISINOPRIL DIHYDRATE
(2000008500)

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

PERINDOPRIL ERBUMINE
(2000008381)

GLENMARK, PLOT NO. 3109- C, GIDC INDUSTRIAL ESTATE,
ANKLESHWAR, DIST. BHARUCH, GUJARAT STATE, IN-393 002, INDIA

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

PARACETAMOL (1000009609)

ANQIU LU'AN PHARMACEUTICAL COMPANY LIMITED, 35 WEIXU
NORTH ROAD, ANQIU CITY, SHANDONG PROVINCE, CN-262 199, CHINA

NOVACYL (WUXI) PHARMACEUTICAL COMPANY LIMITED, 16
GUANGSHI ROAD, MEIJING VILLAGE, LUOSHE TOWN, HUISHAN
DISTRICT, WUXI, JIANGSU PROVINCE, CN-214185, CHINA

ENALAPRIL MALEATE (2000007672)	ZHEJIANG HUAHAI PHARMACEUTICAL CO LIMITED , XUNQIAO, LINHAI CITY, ZHEJIANG PROVINCE, CN-317024, CHINA
PSEUDOEPHEDRINE HYDROCHLORIDE (2000007829)	EMBIO LIMITED , 501 SENTINEL, HIRANANDANI GARDENS, POWAI, MUMBAI, IN-400 076, INDIA
INDAPAMIDE (1000008739)	SUZHOU LIXIN PHARMACEUTICAL CO., LIMITED. , 21 TANGXI ROAD, SUZHOU NEW DISTRICT, SUZHOU, CN-215151, CHINA
CAPTOPRIL (1000006787)	ZHEJIANG HUAHAI PHARMACEUTICAL CO LIMITED , XUNQIAO, LINHAI CITY, ZHEJIANG PROVINCE, CN-317024, CHINA
BENZYL NICOTINATE (1000009481)	HERBERT BROWN PHARMACEUTICAL AND RESEARCH LABORATORIES , W-256-A, MIDC PHASE II, SHIVAJI UDYOG NAGAR, DOMBIVLI, THANE, IN-421203, INDIA
MAGALDRATE (1000001270)	SPI PHARMA, INC , 503 CARR ROAD, WILMINGTON, 19809, UNITED STATES
EPHEDRINE HYDROCHLORIDE (2000007671)	EMBIO LIMITED , 501 SENTINEL, HIRANANDANI GARDENS, POWAI, MUMBAI, IN-400 076, INDIA
IBUPROFEN (1000008918)	SI GROUP , 725 CANNON BRIDGE ROAD, ORANGEBURG, 29115, UNITED STATES

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B	Distribution
	DIMETHICONE (3000011022)
	CETRIMIDE (1000006286)
	SALICYLIC ACID (1000009710)
	ICHTHAMMOL (1000008905)
	DIAZEPAM (1000003208)
	SIMETHICONE (1000009128)
	POLYMYXIN B SULPHATE (4000010173)
	ASPIRIN (1000009870)
	APIXABAN (1000011644)
	LOFEPRAMINE HYDROCHLORIDE (2000008496)
	METHYL SALICYLATE (1000000149)
	CHLORHEXIDINE DIHYDROCHLORIDE (4000002466)
	NYSTATIN (1000009661)
	SODIUM CHLORIDE (1000009536)
	UREA (1000009262)

CHLORHEXIDINE GLUCONATE SOLUTION 20% (4000003482)

LOPERAMIDE HYDROCHLORIDE (2000008494)

AMANTADINE SULPHATE (2000019040)

INDAPAMIDE (1000008739)

LORAZEPAM (1000008543)

PENICILLIN V POTASSIUM (4000007429)

EPINEPHRINE (1000009945)

DOXYLAMINE SUCCINATE (2000007681)

BENZALKONIUM CHLORIDE (2000010983)

CHLORDIAZEPOXIDE HYDROCHLORIDE (2000008104)

CODEINE PHOSPHATE HEMIHYDRATE (4000006570)

PENICILLIN V CALCIUM (4000014135)

MEBEVERINE (1000000255)

PROCAINE HYDROCHLORIDE (2000007906)

CHLORHEXIDINE DIACETATE (4000007351)

CARVEDILOL (1000003761)

BISOPROLOL FUMARATE (2000008290)