

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 | 08/08/2023 |

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

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

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance

PHENOBARBITAL (1000014071)

3rd Country Manufacturer

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

3rd Country Distributor

PHENOBARBITONE (3000014222)	NANTONG JINGHUA PHARMACEUTICAL COMPANY LIMITED , 9 XINGTAI ROAD, ZONE GANGZHA, ECONOMIC DEVELOPMENT, NANTONG, JIANGSU, CN-226005, CHINA
PERINDOPRIL ERBUMINE (2000008381)	GLENMARK , PLOT NO. 3109- C, GIDC INDUSTRIAL ESTATE, ANKLESHWAR, DIST. BHARUCH, GUJARAT STATE, IN-393 002, INDIA
NOSCAPINE (1000009663)	ALKALOIDS CORPORATION , 8 BENTINCK STREET, KOLKATA, IN-700 001, INDIA
PARACETAMOL (1000009609)	ANQIU LU'AN PHARMACEUTICAL COMPANY LIMITED , 35 WEIXU NORTH ROAD, ANQIU CITY, SHANDONG PROVINCE, CN-262 100, CHINA
PSEUDOEPHEDRINE HYDROCHLORIDE (2000007829)	NOVACYL (WUXI) PHARMACEUTICAL COMPANY LIMITED , 16 GUANGSHI ROAD, MEIJING VILLAGE, LUOSHE TOWN, HUIZHAN DISTRICT, WUXI, JIANGSU PROVINCE, CN-214185, CHINA
GRANISETRON (1000009464)	EMBIO LIMITED , 501 SENTINEL, HIRANANDANI GARDENS, POWAI, MUMBAI, IN-400 076, INDIA
PHENYLEPHRINE HYDROCHLORIDE (2000008067)	CIPLA LIMITED , MANUFACTURING & RESEARCH DIVISION, OLD MADRAS ROAD, VIRGONAGAR DISTRICT, BANGALORE, KARNATAKA, IN-560 049, INDIA
PHENYLBUTAZONE (1000009893)	DIVI'S LABORATORIES LIMITED , DIVI TOWERS 7-1-77/E/1/303 DHARAM KARAN ROAD, AMEERPET, HYDERABAD, TELANGANA, IN-500 016, INDIA
MAGALDRATE (1000001270)	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
CLOPIDOGREL BESILATE (2000013668)	SPI PHARMA, INC , 503 CARR ROAD, WILMINGTON, 19809, UNITED STATES
ENALAPRIL MALEATE (2000007672)	CADILA HEALTHCARE LIMITED , ZYDUS TOWER, 5TH FLOOR- SATELLITE CROSS ROADS, SARKHEJ ROAD, GANDHINAGAR, GUJARAT, IN-380015, INDIA
	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
MOMETASONE FUROATE (2000008125)	AURISCO PHARMACEUTICAL LIMITED , ROOM 1709-1710 HITECH PLAZA, NO 488 S WU NING ROAD, SHANGHAI, CN-200 042, CHINA
BENZYL NICOTINATE (1000009481)	HERBERT BROWN PHARMACEUTICAL AND RESEARCH LABORATORIES , W-256-A, MIDC PHASE II, SHIVAJI UDYOG NAGAR, DOMBIVLI, THANE, IN-421203, INDIA
IBUPROFEN (1000008918)	SI GROUP , 725 CANNON BRIDGE ROAD, ORANGEBURG, 29115, UNITED STATES
LISINOPRIL DIHYDRATE (2000008500)	ZHEJIANG HUAHAI PHARMACEUTICAL CO LIMITED , XUNQIAO, LINHAI CITY, ZHEJIANG PROVINCE, CN-317024, CHINA
EPHEDRINE HYDROCHLORIDE (2000007671)	EMBIO LIMITED , 501 SENTINEL, HIRANANDANI GARDENS, POWAI, MUMBAI, IN-400 076, INDIA
CAPTOPRIL (1000006787)	ZHEJIANG HUAHAI PHARMACEUTICAL CO LIMITED , XUNQIAO, LINHAI CITY, ZHEJIANG PROVINCE, CN-317024, CHINA

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B	Distribution
	DIMETHICONE (3000011022)
	BISOPROLOL FUMARATE (2000008290)
	DOXYLAMINE SUCCINATE (2000007681)
	MEBEVERINE (1000000255)
	SODIUM CHLORIDE (1000009536)
	LORAZEPAM (1000008543)
	CHLORHEXIDINE GLUCONATE SOLUTION 20% (4000003482)
	POLYMYXIN B SULPHATE (4000010173)
	PROCAINE HYDROCHLORIDE (2000007906)
	PENICILLIN V POTASSIUM (4000007429)
	METHYL SALICYLATE (1000000149)
	AMANTADINE SULPHATE (2000019040)
	SALICYLIC ACID (1000009710)
	CHLORHEXIDINE DIHYDROCHLORIDE (4000002466)
	CHLORDIAZEPOXIDE HYDROCHLORIDE (2000008104)
	ICHTHAMMOL (1000008905)
	NYSTATIN (1000009661)
	APIXABAN (1000011644)

CARVEDILOL (1000003761)
CODEINE PHOSPHATE HEMIHYDRATE (4000006570)
BENZALKONIUM CHLORIDE (2000010983)
PENICILLIN V CALCIUM (4000014135)
EPINEPHRINE (1000009945)
SIMETHICONE (1000009128)
CHLORHEXIDINE DIACETATE (4000007351)
UREA (1000009262)
CETRIMIDE (1000006286)
ASPIRIN (1000009870)
DIAZEPAM (1000003208)
LOFEPRAMINE HYDROCHLORIDE (2000008496)
LOPERAMIDE HYDROCHLORIDE (2000008494)