

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 | 26/06/2024 |

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

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

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance

PHENOBARBITONE
(3000014222)

3rd Country Manufacturer

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

3rd Country Distributor

CLOPIDOGREL BESILATE
(2000013668)

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

LISINAPRIL 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

PHENYLBUTAZONE
(1000009893)

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

BENZYL NICOTINATE
(1000009481)

**HERBERT BROWN PHARMACEUTICAL AND RESEARCH
LABORATORIES**, W-256-A, MIDC PHASE II, SHIVAJI UDYOG NAGAR,
DOMBIVLI, THANE, IN-421203, INDIA

PSEUDOEPHEDRINE
HYDROCHLORIDE
(2000007829)

EMBIO LIMITED, 501 SENTINEL, HIRANANDANI GARDENS, POWAI,
MUMBAI, IN-400 076, INDIA

IBUPROFEN (1000008918)

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

PHENOBARBITAL (1000014071)

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

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

MOMETASONE FUROATE
(2000008125)

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

MAGALDRATE (1000001270)

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

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, ANQIU CITY, SHANDONG PROVINCE, CN-262 100, CHINA

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| ENALAPRIL MALEATE (2000007672) | ZHEJIANG HUAHAI PHARMACEUTICAL CO LIMITED , XUNQIAO, LINHAI CITY, ZHEJIANG PROVINCE, CN-317024, CHINA |
| GRANISETRON (1000009464) | CIPLA LIMITED , MANUFACTURING & RESEARCH DIVISION, OLD MADRAS ROAD, VIRGONAGAR DISTRICT, BANGALORE, KARNATAKA, IN-560 049, INDIA |
| EPHEDRINE HYDROCHLORIDE (2000007671) | EMBIO LIMITED , 501 SENTINEL, HIRANANDANI GARDENS, POWAI, MUMBAI, IN-400 076, INDIA |
| PERINDOPRIL ERBUMINE (2000008381) | GLENMARK , PLOT NO. 3109- C, GIDC INDUSTRIAL ESTATE, ANKLESHWAR, DIST. BHARUCH, GUJARAT STATE, IN-393 002, INDIA |
| CAPTOPRIL (1000006787) | ZHEJIANG HUAHAI PHARMACEUTICAL CO LIMITED , XUNQIAO, LINHAI CITY, ZHEJIANG PROVINCE, CN-317024, CHINA |
| NOSCAPINE (1000009663) | ALKALOIDS CORPORATION , 8 BENTINCK STREET, KOLKATA, IN-700 001, INDIA |
| ALUMINIUM HYDROXIDE (1000013126) | SPI PHARMA, INC , 503 CARR ROAD, WILMINGTON, 19809, UNITED STATES |

2. IMPORTATION AND DISTRIBUTION OPERATIONS

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|---|---|
| B | Distribution |
| | PENICILLIN V CALCIUM (4000014135) |
| | AMANTADINE SULPHATE (2000019040) |
| | APIXABAN (1000011644) |
| | POLYMYXIN B SULPHATE (4000010173) |
| | ICHTHAMMOL (1000008905) |
| | BISOPROLOL FUMARATE (2000008290) |
| | EPINEPHRINE (1000009945) |
| | SODIUM CHLORIDE (1000009536) |
| | CHLORHEXIDINE GLUCONATE SOLUTION 20% (4000003482) |
| | ASPIRIN (1000009870) |
| | DIMETHICONE (3000011022) |
| | CARVEDILOL (1000003761) |
| | METHYL SALICYLATE (1000000149) |
| | UREA (1000009262) |
| | PROCAINE HYDROCHLORIDE (2000007906) |
| | MEBEVERINE (1000000255) |
| | LOFEPRAMINE HYDROCHLORIDE (2000008496) |
| | CODEINE PHOSPHATE HEMIHYDRATE (4000006570) |

CETRIMIDE (1000006286)
CHLORDIAZEPOXIDE HYDROCHLORIDE (2000008104)
LORAZEPAM (1000008543)
CHLORHEXIDINE DIHYDROCHLORIDE (4000002466)
SIMETHICONE (1000009128)
DIAZEPAM (1000003208)
SALICYLIC ACID (1000009710)
DOXYLAMINE SUCCINATE (2000007681)
NYSTATIN (1000009661)
PENICILLIN V POTASSIUM (4000007429)
BENZALKONIUM CHLORIDE (2000010983)
CHLORHEXIDINE DIACETATE (4000007351)
LOPERAMIDE HYDROCHLORIDE (2000008494)