

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 39574 |
| 2. Name or corporate name of registrant | FAGRON UK LIMITED |
| 3. Permanent or legal address of registrant | FAGRON UK LIMITED, MEDIA EXCHANGE, 4B COQUET STREET,
NEWCASTLE UPON TYNE, NE1 2QB, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | FAGRON UK LIMITED, MEDIA EXCHANGE, 4B COQUET STREET,
NEWCASTLE UPON TYNE, NE1 2QB, 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 | 02/06/2025 |

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

FAGRON UK LIMITED, MEDIA EXCHANGE, 4B COQUET STREET, NEWCASTLE UPON TYNE, NE1 2QB, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
GLYCOPYRRONIUM BROMIDE (2000011773)	SWATI SPENTOSE PRIVATE LIMITED , UNIT-I, PLOT NUMBER A-1/2102, 2103 AND A-2/2120, PHASE III, G.I.D.C., DISTRICT VALSAD, VAPI, GUJARAT, IN-396195, INDIA	

SILDENAFIL CITRATE (2000006954)	SMS LIFESCIENCES INDIA LIMITED, KHAZIPALLY VILLAGE, JINNARAM MANDAL, HYDERABAD, MEDAK DISTRICT, IN-502 319, INDIA	
TESTOSTERONE MICRONISED (2000018723)	JIANGSU JIAERKE PHARMACEUTICALS GROUP CORP LIMITED, SANHUANGMIAO, WUJIN, CHANGZHOU, ZHENGLU, JIANGSU, CN-213 111, CHINA	
CHLOROTHIAZIDE (1000004605)	CTX LIFESCIENCES PVT LIMITED., BLOCK NO. 251-252, SACHIN-MAGDALLA ROAD, GIDC, SACHIN, SURAT, GUJARAT, IN-394 230, INDIA	
PREGNENOLONE (1000011186)	JIANGSU JIAERKE PHARMACEUTICALS GROUP CORP LIMITED, SANHUANGMIAO, WUJIN, CHANGZHOU, ZHENGLU, JIANGSU, CN-213 111, CHINA	
SUCRALFATE (1000009411)	ZHEJIANG HAISEN PHARMACEUTICAL CO LIMITED, LIUSHI STREET, DONGYANG CITY, ZHEJIANG, CN-322104, CHINA	
TADALAFIL (1000000162)	ZHEJIANG HUAHAI PHARMACEUTICAL CO.LTD, XUNQIAO, LINHAI CITY, ZHEJIANG PROVINCE, CN-317024, CHINA	
ADRENALINE TARTRATE (4000006411)	WUHAN WUYAO PHARMACEUTICAL CO., LIMITED, 18 WANGFEN ROAD, FUCHI TOWN, YANGXIN COUNTY, HUANGSHI CITY, HUBEI, CN-435 229, CHINA	
KETOCONAZOLE (1000008441)	AARTI DRUGS LIMITED, PLOT NO. E-21, M.I.D.C. TARAPUR, PALGHAR, MAHARASHTRA, IN 401506, INDIA	TRINITY PHARMACEUTICALS AND FOOD PRIVATE LIMITED, UNIT 813, 8TH FLOOR, KANAKAI WALL STREET, CHAKALA, ANDHERI KURLA ROAD, MUMBAI, MAHARASHTRA, IN- 400093, INDIA
FINASTERIDE (1000007415)	HUBEI GEDIAN HUMANWELL PHARMACEUTICAL CO, LIMITED., NO. 199 JIAN SHE AVENUE, GEDIAN ECONOMIC DEVELOPMENT DISTRICT, EZHOU, HUBEI, CN-436070, CHINA	HUBEI GEDIAN HUMANWELL PHARMACEUTICAL CO, LIMITED., NO. 199 JIAN SHE AVENUE, GEDIAN ECONOMIC DEVELOPMENT DISTRICT, EZHOU, HUBEI, CN- 436070, CHINA

KUMAR ORGANICS PRODUCTS LIMITED,
MINOXIDIL (1000000832) PLOT NO. 60, 62, 64-65, ROAD NO. 3 & 5,
JIGANI INDUSTRIAL AREA, ANEKAL TALUK,
BANGALORE, KARNATAKA, IN-560 105, INDIA

SWATI SPENTOSE PRIVATE LIMITED, UNIT-I,
DUTASTERIDE PLOT NUMBER A-1/2102, 2103 AND A-2/2120,
(1000007791) PHASE III, G.I.D.C., DISTRICT VALSAD, VAPI,
GUJARAT, IN-396195, INDIA

ZHEJIANG HISUN PHARMACEUTICAL CO.
IVERMECTIN **LIMITED,** 56 BINHAI ROAD, JIAOJIANG
(1000001158) DISTRICT, TAIZHOU CITY, ZHEJIANG
PROVINCE, CN-318000, CHINA

SPECGX LLC, 3600 NORTH SECOND STREET,
NALTREXONE HYDROCHLORIDE ST LOUIS, 63147, UNITED STATES
(2000007614)

JIANGSU JIAERKE PHARMACEUTICALS
PRASTERONE **GROUP CORP LIMITED,** SANHUANGMIAO,
(1000006301) WUJIN, CHANGZHOU, ZHENGLU, JIANGSU,
CN-213 111, CHINA

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution
TACROLIMUS (1000002882)
MAGNESIUM STEARATE (1000008714)
AMPHOTERICIN B (1000012483)
GLYCOPYRRONIUM BROMIDE (2000011773)
BECLOMETASONE DIPROPIONATE (4000006191)
HYDROCHLOROTHIAZIDE (1000008764)
POTASSIUM DIHYDROGEN PHOSPHATE (4000011338)
CHLORAMPHENICOL MICRONISED (3000020176)
CHLORHEXIDINE DIGLUCONATE SOLUTION 20% (4000003169)
MAGNESIUM CARBONATE HEAVY (2000008430)
PYRIDOXINE HYDROCHLORIDE (4000010966)
VITAMIN A PALMITATE (4000006828)
GLUCOSE ANHYDROUS (4000009250)
QUININE HYDROCHLORIDE (2000007815)
TROMETAMOL HYDROCHLORIDE (2000003893)
TOPIRAMATE (1000002932)
LOCUST BEAN GUM (3000001000)
LIDOCAINE HYDROCHLORIDE (2000014083)

FUROSEMIDE (3000005943)
BETAMETHASONE VALERATE (2000008358)
MACROGOL 6000 (3000003702)
CHLORHEXIDINE HYDROCHLORIDE (2000008100)
SILDENAFIL CITRATE (2000006954)
TESTOSTERONE MICRONISED (2000018723)
GALACTOSE (1000008044)
NICOTINAMIDE (2000012339)
TRYPTOPHAN (1000009274)
CHLOROBUTANOL HEMIHYDRATE (2000011272)
ACETYLCYSTEINE (1000009816)
DISODIUM PHOSPHATE DODECAHYDRATE (3000014453)
DITHRANOL (1000002937)
PREDNISOLONE SODIUM PHOSPHATE (2000007914)
AMIODARONE HYDROCHLORIDE (2000008524)
CHLOROTHIAZIDE (1000004605)
ATROPINE SULPHATE (2000008446)
NIFEDIPINE (1000009680)
CETIRIZINE DIHYDROCHLORIDE (4000006373)
GABAPENTIN (1000007380)
ALUMINIUM SULPHATE (1000002620)
LACTOSE (1000008197)
SALICYLIC ACID (1000009710)
GRISEOFULVIN (1000001953)
MINOCYCLINE HYDROCHLORIDE (2000008251)
CALCIUM LACTATE PENTAHYDRATE (4000009405)
BENZOIC ACID (1000009143)
ESTRADIOL (1000017043)
CLONIDINE HYDROCHLORIDE (2000008010)
THYROID (1000007072)
HYDROCORTISONE ACETATE (2000007338)
BACLOFEN (1000009324)
LATANOPROST (1000003257)
CALCIUM CHLORIDE DIHYDRATE (4000009373)
CAMPOR RACEMIC (4000000347)
CLIOQUINOL (1000004182)
ALUMINIUM OXIDE HYDRATED (3000010996)
BENZOCAINE (1000009160)
FLUORESCEIN SODIUM (2000007506)
PHENOXYETHANOL (1000009898)
AMOXICILLIN (3000006129)

L-CITRULLINE (3000016930)
ISONIAZID (1000007745)
BENZALKONIUM CHLORIDE (2000010983)
AZITHROMYCIN (1000009476)
CLOZAPINE (1000009115)
YELLOW SOFT PARAFFIN (4000006813)
L-ARGININE HYDROCHLORIDE (4000006512)
MIDAZOLAM HYDROCHLORIDE (2000008252)
CLOBAZAM (1000004171)
DIAZEPAM (1000003208)
ESTRADIOL BENZOATE (2000016107)
BETAMETHASONE DIPROPIONATE (2000008360)
SULPHUR (1000009383)
PREGNENOLONE (1000011186)
MICONAZOLE NITRATE (2000008254)
CYSTEINE HYDROCHLORIDE (2000007859)
PAPAVERINE HYDROCHLORIDE (2000008091)
CAFFEINE (1000007507)
MAGNESIUM GLYCEROPHOSPHATE (2000012211)
ALLOPURINOL (1000003843)
ACETYLSALICYLIC ACID (3000006351)
COPPER SULPHATE (2000007927)
MACROGOL 400 (1000008642)
TETRACYCLINE HYDROCHLORIDE (2000007377)
PEPPERMINT OIL (4000010071)
ZINC GLUCONATE (2000005863)
AZELAIC ACID (1000007411)
LEVOMEPRMAZINE MALEATE (2000012271)
BORIC ACID (1000007337)
NITROFURANTOIN (1000009675)
PROPRANOLOL HYDROCHLORIDE (2000007892)
BUDESONIDE (1000007214)
CITRIC ACID MONOHYDRATE (2000008022)
WARFARIN SODIUM (2000008471)
PERMETHRIN (1000009478)
TESTOSTERONE PROPIONATE (2000007380)
THIAMINE HYDROCHLORIDE (4000010937)
AMBROXOL HYDROCHLORIDE (2000006335)
CLOBETASONE BUTYRATE (2000008013)
HYDROXOCOBALAMIN CHLORIDE (4000010981)
GLUCOSE (1000012489)

AMITRIPTYLINE HYDROCHLORIDE (2000008522)
TETRACAINE HYDROCHLORIDE (2000010807)
ENALAPRIL MALEATE (2000007672)
BORAX (1000007346)
TOCOFERSOLAN (4000012967)
CHLORAL HYDRATE (1000005193)
NEOMYCIN SULPHATE MICRONISED (2000018721)
TOBRAMYCIN SULPHATE (2000008597)
SODIUM BICARBONATE (1000009540)
CYPROTERONE ACETATE (2000007860)
GENTAMICIN SULFATE (4000011668)
CAPTOPRIL (1000006787)
MACROGOL 1000 (1000007757)
NEOMYCIN SULPHATE (2000008175)
COCAINE HYDROCHLORIDE (2000007943)
PARACETAMOL (1000009609)
7-KETO-DEHYDROEPIANDROSTERONE (1000019708)
SPIRONOLACTONE MICRONISED (2000018722)
PREDNISOLONE (1000009794)
DISODIUM PHOSPHATE ANHYDROUS (3000006909)
TRICHLOROACETIC ACID (1000007071)
DIMETHICONE 1000 (4000009592)
BUPIVACAINE HYDROCHLORIDE (2000008278)
SODIUM THIOSULPHATE (1000007419)
FLUOXETINE HYDROCHLORIDE (2000008390)
TRETINOIN (1000009303)
GLYCEROL (1000001659)
SODIUM CITRATE (1000009535)
ESTRADIOL HEMIHYDRATE (2000016108)
RIBOFLAVIN SODIUM PHOSPHATE (4000007238)
CAFFEINE CITRATE (2000008271)
BENZALKONIUM CHLORIDE SOLUTION 50% (4000007313)
GLUCOSE MONOHYDRATE (4000006254)
CALCIUM GLUCONATE MONOHYDRATE (4000009385)
HYDROXYETHYLCELLULOSE (1000008666)
DISODIUM PHOSPHATE DIHYDRATE (3000014468)
CARBAMAZEPINE (1000006757)
CHLORPHENIRAMINE MALEATE (2000008095)
POTASSIUM CHLORIDE (1000009818)
ICHTHAMMOL (1000008905)
L-ARGININE (3000004673)

CIPROFLOXACIN HYDROCHLORIDE (2000008038)
MACROGOL 300 (1000009031)
CHLOROFORM (1000004649)
AMMONIUM CHLORIDE (1000008021)
CALCIUM CITRATE ANHYDROUS (4000009380)
PROFLAVINE HEMISULPHATE (2000007900)
CALAMINE (1000007496)
CALCIUM CARBONATE HEAVY (4000007498)
FLUOCINOLONE ACETONIDE (2000007511)
ADAPALENE (1000002293)
DEFEROXAMINE MESYLATE (4000006726)
SUCRALFATE (1000009411)
HYDROQUINONE (1000008752)
ZINC PYRITHIONE (4000008930)
TRANEXAMIC ACID (1000009308)
METOPROLOL TARTRATE (2000008259)
ALIMEMAZINE TARTRATE (4000006319)
HYDROXYCHLOROQUINE SULFATE (4000006673)
NADOLOL (1000000391)
CLOTRIMAZOLE (1000003999)
LEVOTHYROXINE SODIUM (2000013292)
BISMUTH SUBGALLATE (2000008349)
HISTIDINE (1000008814)
CANNABIDIOL (1000000540)
MAGNESIUM OXIDE (1000000883)
AZATHIOPRINE (1000009761)
PROGESTERONE (1000009777)
CLOBETASOL 17-PROPIONATE (4000007268)
PHENYLEPHRINE HYDROCHLORIDE (2000008067)
L-METHIONINE (3000004549)
WHITE SOFT PARAFFIN (4000006817)
TETRACAINE (1000012475)
BENDROFLUMETHIAZIDE (3000006463)
LEVOMENTHOL NATURAL (3000003005)
GLYCEROL MONOSTEARATE (3000001363)
FRUCTOSE (1000002379)
TADALAFIL (1000000162)
LACTIC ACID (1000008218)
METFORMIN HYDROCHLORIDE (2000008338)
DEXTROMETHORPHAN HYDROBROMIDE (2000007835)
CITRIC ACID ANHYDROUS (3000004479)

HYDROCORTISONE (1000008762)
MAGNESIUM SULPHATE HEPTAHYDRATE (4000009924)
AMISULPRIDE (1000003074)
ADRENALINE TARTRATE (4000006411)
KETOCONAZOLE (1000008441)
DL-ALPHA TOCOPHEROL (4000011023)
CLINDAMYCIN HYDROCHLORIDE (2000006497)
UREA (1000009262)
AMILORIDE HYDROCHLORIDE (2000008529)
PHENOL (1000009902)
OXYBUTYNIN HYDROCHLORIDE (2000008318)
OXETACAINE (3000004664)
CALCIUM HYDROGEN PHOSPHATE (2000008265)
FOLIC ACID (1000001996)
DEXAMETHASONE (1000003334)
POVIDONE-IODINE (1000009800)
MAGNESIUM CHLORIDE (2000012207)
CALCIUM CARBONATE LIGHT (2000006127)
ALLANTOIN (1000004055)
POTASSIUM IODIDE (1000009810)
FINASTERIDE (1000007415)
THEOPHYLLINE (1000009347)
DOXYCYCLINE HYCLATE (4000006937)
NITRAZEPAM (1000009676)
MINOXIDIL (1000000832)
TRIAMCINOLONE MICRONISED (2000018724)
QUINIDINE SULPHATE (2000007818)
CINNARIZINE (1000004760)
DIMETHYL SULFOXIDE (3000005283)
PHENOBARBITAL (1000014071)
PHENYTOIN (1000009887)
NORADRENALINE TARTRATE (4000003578)
CHLORHEXIDINE ACETATE (2000008103)
L-GLUTATHIONE REDUCED (3000024400)
MAGNESIUM CHLORIDE HEXAHYDRATE (4000009913)
CADE OIL (4000009842)
DUTASTERIDE (1000007791)
SODIUM CHLORIDE (1000009536)
AMLODIPINE BESILATE (2000015864)
CASTOR OIL (2000011186)
IODINE (1000008377)

METHENAMINE (1000000630)
IVERMECTIN (1000001158)
BUMETANIDE (1000007192)
ESTRIOL (3000004591)
CHLORHEXIDINE DIACETATE (4000007351)
CHLORHEXIDINE GLUCONATE SOLUTION 20% (4000003482)
BISACODYL (1000007386)
MEXILETINE HYDROCHLORIDE (2000008257)
KETAMINE HYDROCHLORIDE (2000008609)
NALTREXONE HYDROCHLORIDE (2000007614)
HYDROCORTISONE BUTYRATE (2000007337)
TOCOPHERYL ACETATE (4000010502)
PRASTERONE (1000006301)
DICLOFENAC SODIUM (2000007774)
GLYCINE (1000012477)
HYDROXYZINE HYDROCHLORIDE (2000007325)
DAPSONE (1000003787)
QUININE SULFATE (4000007240)
OXYTOCIN (1000009622)
EOSIN (1000005976)
COCONUT OIL (2000007942)
PREGNENOLONE ACETATE (2000009822)
DIMETHICONE 350 (4000009591)
PHENOL CRYSTALS (3000020190)
VANCOMYCIN HYDROCHLORIDE (2000008485)
URIDINE (1000006884)
FERRIC CHLORIDE HEXAHYDRATE (4000004546)
SODIUM DIHYDROGEN PHOSPHATE (3000010117)
METHIONINE (1000000542)
ESTRADIOL (17-ALPHA) (3000021667)
SODIUM BENZOATE (2000013061)
BENZOYL PEROXIDE (1000009105)
LOPERAMIDE HYDROCHLORIDE (2000008494)
QUININE DIHYDROCHLORIDE (2000007816)
MANNITOL (1000000458)
CLOPIDOGREL BISULFATE (4000011216)
HYOSCINE BUTYLBROMIDE (2000007324)
MELATONIN (1000000731)
ZINC OXIDE (2000008399)
PREDNISONE (1000009793)
MICONAZOLE (1000001002)

L-CARNITINE (3000007571)
THEOPHYLLINE MONOHYDRATE (4000006918)
DILTIAZEM HYDROCHLORIDE (2000007763)
METRONIDAZOLE (1000001131)
LEVOMENTHOL SYNTHETIC (3000003004)
CHOLESTEROL (1000004479)
POTASSIUM CITRATE (1000009817)
MACROGOL 4000 (2000012180)
CYANOCOBALAMIN (4000010977)
DISODIUM EDETATE (2000007753)
TRIAMCINOLONE ACETONIDE (2000008586)
KETOPROFEN (1000008346)
OMEPRazole (1000009101)
MAGNESIUM TRISILICATE (1000000774)
CETRIMIDE (1000006286)
RIBOFLAVIN (4000010954)
DIAZOXIDE (1000003204)
TROMETAMOL (1000009280)
CHOLECALCIFEROL (2000008032)
ERGOCALCIFEROL (2000007667)
PHENOBARBITAL SODIUM (2000008072)
CAPSAICIN (1000006807)
METHYL SALICYLATE (1000000149)
MACROGOL 1500 (1000008431)
NYSTATIN (1000009661)
ALMOND OIL (4000010203)