

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 39541 |
| 2. Name or corporate name of registrant | ASCOT LABORATORIES LIMITED |
| 3. Permanent or legal address of registrant | ASCOT LABORATORIES LIMITED, 1 WARWICK PLACE, WARWICK ROAD, BOREHAMWOOD, WD6 1UA, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | ASCOT LABORATORIES LIMITED, 1 WARWICK PLACE, WARWICK ROAD, BOREHAMWOOD, WD6 1UA, 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 | 29/09/2025 |

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

ASCOT LABORATORIES LIMITED, 1 WARWICK PLACE, WARWICK ROAD, BOREHAMWOOD, WD6 1UA, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
ORPHENADRINE CITRATE (2000008058)	HARIKA DRUGS PRIVATE LIMITED , SURVEY NO. 165/A & 165/E, GUMMADIDALA VILLAGE, MEDAK DISTRICT, TELANGANA, IN-500 038, INDIA	
OMEPRazole (1000009101)	LEE PHARMA LIMITED , SURVEY NO. 10/G-1, GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, IN 502319, INDIA	

AMLODIPINE BESILATE (2000015864)	IPCA LABORATORIES LIMITED , PLOT NO.H-4, MIDC, WALUJ, CHHATRAPATI SAMBHAJINAGAR, MAHARASHTRA, IN-431136, INDIA
SODIUM BENZOATE (2000013061)	GANESH BENZOPLAST LIMITED , D-21/2/2 MIDC INDUSTRIAL AREA, TARAPUR, MAHARASHTRA, IN-401506, INDIA
TOPIRAMATE (1000002932)	MSN ORGANICS PRIVATE LIMITED , SURVEY NUMBER 224/A, BIBINAGAR MANDAL, YADADRI BHUVANAGIRI DISTRICT, BIBINAGAR VILLAGE, TELANGANA, IN-508126, INDIA
IVERMECTIN (1000001158)	BAJAJ HEALTHCARE LIMITED , UNIT II, BLOCK NO 588, SAVLI-KARACHIA ROAD, SAVLI, VANDODARA, GOTHADA, GUJARAT, IN-391776, INDIA
TRANEXAMIC ACID (1000009308)	AMI LIFESCIENCES PRIVATE LIMITED , BLOCK NO. 82/B, ECP ROAD, AT & PO, KARAKHADI, TA. PADRA, BARODA, IN 391450, INDIA
CLOPIDOGREL BISULFATE (4000011216)	PRAVEEN LABORATORIES PRIVATE LIMITED , BLOCK NO. 206, PALSANA TALUKA, JOLWA VILLAGE, SURAT, GUJARAT, IN-394305, INDIA
FLUNARIZINE DIHYDROCHLORIDE (4000009677)	FLEMING LABORATORIES LIMITED , SURVEY NUMBER 270, NAWABPET VILLAGE, SIVAMPET MANDAL, MEDAK DISTRICT, TELANGANA, IN-502313, INDIA
PRAZOSIN HYDROCHLORIDE (2000007918)	NURAY CHEMICALS PRIVATE LIMITED , GROUND FLOOR, PLOT NUMBER 111, SIDCO INDUSTRIAL ESTATE, KAKKALUR, THIRUVALLUR, TAMIL NADU, IN-602003, INDIA
MELATONIN (1000000731)	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
ZONISAMIDE (1000003230)	ENAL DRUGS PRIVATE LIMITED , D-33, 34 & 35, PHASE 1, IDA, JEEDIMETLA, HYDERABAD, IN-500055, INDIA
CYCLIZINE HYDROCHLORIDE (2000007923)	SRIKEM LABORATORIES PRIVATE LIMITED , PLOT NO. 17/22, 17/23, 17/24, 17/13 MIDC, TALOJA, NAVI MUMBAI, MAHARASHTRA, IN-410 208, INDIA
METFORMIN HYDROCHLORIDE (2000008338)	AURO LABORATORIES LIMITED , NAVAPUR ROAD, K-56 MIDC, BOISAR, DISTRICT TARAPUR, MAHARASHTRA, IND-401506, INDIA
FINASTERIDE (1000007415)	HUNAN YUXIN PHARMACEUTICAL COMPANY LIMITED , LONGXUTANG, SHAORYANG, HUNAN, CN-422001, CHINA

CAPSAICIN (1000006807)

AUDI PHARMACEUTICALS PRIVATE LIMITED, D/9/B, 27TH CROSS STREET,
MAHARAJANAGAR, TIRUNELVELI, TAMIL NADU, IN-627011, INDIA

CLONIDINE
HYDROCHLORIDE
(2000008010)

ALEMBIC PHARMACEUTICALS LIMITED, UNIT I, P.O. TAJPURA, NEAR
BASKA, TALUKA HALOL, PANCHMAHAL DISTRICT, PANELAV VILLAGE,
GUJARAT, IN-389350, INDIA

SULFAPYRIDINE
(3000017230)

VIRCHOW DRUGS LIMITED, SURVEY NO. 639, TEMPLE ROAD,
BONTHAPALLY VILLAGE, GUMMADIDALA MANDAL, SANGAREDDY
DISTRICT, TELANGANA, IN 502313, INDIA

NADOLOL (1000000391)

AZICO BIOPHORE INDIA PRIVATE LIMITED, PLOT NO. 40/A, JN
PHARMACITY, PARAWADA MANDAL, ANAKAPALLI, ANDHRA PRADESH, IN-
531021, INDIA

LEVOTHYROXINE SODIUM
(2000013292)

AUORE PHARMACEUTICALS PRIVATE LIMITED, UNIT 1, PLOT NOS. 35, 36,
38 TO 40, 49 TO 51, PHASE IV, I.D.A., JEEDIMETLA, HYDERABAD,
TELANGANA, IN 500055, INDIA

RASAGILINE MESYLATE
(2000005590)

GLENMARK PHARMACEUTICALS LIMITED, PLOT NO. 3109, G.I.D.C.
INDUSTRIAL ESTATE, ANKLESHWAR, BHARUCH DISTRICT, GUJARAT, IN
393002, INDIA

VALGANCICLOVIR
HYDROCHLORIDE
(2000006980)

AUORE PHARMACEUTICALS PRIVATE LIMITED, UNIT 1, PLOT NOS. 35, 36,
38 TO 40, 49 TO 51, PHASE IV, I.D.A., JEEDIMETLA, HYDERABAD,
TELANGANA, IN 500055, INDIA

SPIRONOLACTONE
(1000009436)

TIANJIN JINJIN PHARMACEUTICAL COMPANY LIMITED, 8 JINGFU ROAD,
INDUSTRIAL ZONE OF ZHANGJIAWO TOWN, XIQING DISTRICT, TIANJIN, CN-
300387, CHINA

CHLOROTHIAZIDE
(1000004605)

CTX LIFESCIENCES PRIVATE LIMITED, BLOCK NO. 251-252, SACHIN-
MAGDALLA ROAD, GIDC, SACHIN, SURAT, GUJARAT, IN-394 230, INDIA

MEXILETINE
HYDROCHLORIDE
(2000008257)

BIOPHORE INDIA PHARMACEUTICALS PRIVATE LIMITED, PLOT NO. 80A,
ROAD NO: 05, JAWAHARLAL NEHRU PHARMA CITY, E.BONANGI (VILLAGE),
PARAWADA (MANDAL), VISAKHAPATNAM, ANDHRA PRADESH, IN-531021,
INDIA

PARACETAMOL
(1000009609)

FARMSON PHARMACEUTICAL GUJARAT PRIVATE LIMITED, PLOT NO. 14
GIDC INDUSTRIAL ESTATE, NANDESARI, VADODARA DISTRICT, GUJARAT,
IN-391340, INDIA

HALOPERIDOL (1000001486)	RPG LIFE SCIENCES LIMITED , 25 MIDC LAND, THANE-BELAPUR ROAD, NAVI MUMBAI, MAHARASHTRA, IN-400 703, INDIA
CLOBETASOL PROPIONATE (2000008014)	SYMBIOTICA SPECIALITY INGREDIENTS SDN. BHD , NO. 518 JALAN WAJA 4, WAJA INDUSTRIAL ESTATE, KULIM, KEDAH, MY-09000, MALAYSIA
CARVEDILOL (1000003761)	CADILA PHARMACEUTICALS LIMITED , PLOT NO. 294 GIDC INDUSTRIAL ESTATE, BHARUCH DISTRICT, ANKLESHWAR, GUJARAT, IN-393002, INDIA
EOSIN (1000005976)	JPN PHARMA PRIVATE LIMITED , T-108/109, MIDC, TARAPUR, BOISAR, THANE DISTRICT, MAHARASHTRA, IN-401 506, INDIA
PYRAZINAMIDE (1000009751)	ANUH PHARMA LIMITED , E-17/3 & E-17/4 & E-18 M.I.D.C., BOISAR, TARAPUR, TALUKA PALGHAR, THANE, MAHARASHTRA, IN-401506, INDIA
METHOXSALEN (1000007442)	SOLARA ACTIVE PHARMA SCIENCES LIMITED , 120 A & B, 36, 120P &121, INDUSTRIAL AREA, BAIKAMPADY, NEW MANGALORE, KARNATAKA, IN- 575011, INDIA
RAMIPRIL (1000009080)	MELODY HEALTHCARE PRIVATE LIMITED , PLOT NO. J-73, MIDC, DIST. PALGHAR, TARAPUR, MAHARASHTRA, IN-401506, INDIA
OXANDROLONE (1000016028)	NURAY CHEMICALS PRIVATE LIMITED , GROUND FLOOR, PLOT NUMBER 111, SIDCO INDUSTRIAL ESTATE, KAKKALUR, THIRUVALLUR, TAMIL NADU, IN-602003, INDIA
SODIUM PHENYLBUTYRATE (2000005746)	SRI KRISHNA PHARMACEUTICALES LIMITED , UNIT III, SURVEY NO 57, GOLKONDA KALAN, RAIKUNTA VILLAGE, SHAMSHABAD MANDAL, TELANGANA, IN-501218, INDIA
CAFFEINE (1000007507)	SHANDONG XINHUA PHARMACEUTICAL CO. LIMITED , EAST CHEMICAL ZONE OF ZIBO HIGH & NEW TECHNOLOGY DEVELOPMENT ZONE, ZHANGDIAN DISTRICT, ZIBO, SHANDONG, CN-255 075, CHINA
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
METOLAZONE (1000001205)	AZICO BIOPHORE INDIA PRIVATE LIMITED , PLOT NO. 40/A, JN PHARMACITY, PARAWADA MANDAL, ANAKAPALLI, ANDHRA PRADESH, IN- 531021, INDIA

DILTIAZEM HYDROCHLORIDE (2000007763)	DIVI'S LABORATORIES LIMITED , UNIT 1, LINGOJIGUDEM VILLAGE, CHOUTUPPAL MANDAL, YADADRI BHUVANAGIRI DISTRICT, TELANGANA, IN-508252, INDIA
BISACODYL (1000007386)	JPN PHARMA PRIVATE LIMITED , T-108/109, MIDC, TARAPUR, BOISAR, THANE DISTRICT, MAHARASHTRA, IN-401 506, INDIA
AZATHIOPRINE (1000009761)	RPG LIFE SCIENCES LIMITED , 25 MIDC LAND, THANE-BELAPUR ROAD, NAVI MUMBAI, MAHARASHTRA, IN-400 703, INDIA
MIDAZOLAM HYDROCHLORIDE (2000008252)	LAKE CHEMICALS PRIVATE LIMITED , SITE NO 21M, ATTIBELE INDUSTRIAL AREA, ANEKAL TALUK, BENGALURU, KARNATAKA, IN-562 107, INDIA
MINOXIDIL (1000000832)	KUMAR ORGANIC PRODUCTS LIMITED , PLOT NO. 60 & 65, ROAD NO. 3, JIGANI INDUSTRIAL AREA, ANEKAL TALUK, BANGALORE, KARNATAKA, IN- 560 105, INDIA
SOLIFENACIN SUCCINATE (2000006491)	MICRO LABORATORIES LIMITED , PLOT 43-45 KIADB, ANEKAL TALUK, BOMMASANDRA-JIGANI LINK ROAD, BENGALURU, KARNATAKA, IN-560105, INDIA
TACROLIMUS MONOHYDRATE (2000016490)	CONCORD BIOTECH LIMITED , 1482-1486 TRASAD ROAD, DHOLKA, AHMEDABAD DISTRICT, GUJARAT, IN-382 225, INDIA
NITAZOXANIDE (1000000749)	AZICO BIOPHORE INDIA PRIVATE LIMITED , PLOT NO. 40/A, JN PHARMACITY, PARAWADA MANDAL, ANAKAPALLI, ANDHRA PRADESH, IN- 531021, INDIA
DITHRANOL (1000002937)	SUJALAM CHEMICALS , A-43 M.I.D.C., KURKUMBH, TAL, DAUND, DISTRICT PUNE, IN-413802, INDIA
MONOBENZONE (1000019033)	CHANGZHOU SUNLIGHT PHARMACEUTICAL COMPANY LIMITED , 216 YUNNAN WEST ROAD, BENNIU TOWN, XINBEI DISTRICT, CHANGZHOU CITY, JIANGSU PROVINCE, CN 213134, CHINA
TELMISARTAN (1000008495)	CALYX CHEMICALS AND PHARMACEUTICALS LIMITED , N/102/91/90 MIDC, TARAPUR, BOISAR, PALGHAR DISTRICT, MAHARASHTRA, IN-401 506, INDIA
LEVAMISOLE HYDROCHLORIDE (2000006314)	NANJING WHITE WHALE PHARMA , NO. 29 FANGSHUIDONG ROAD, NANJING JIANBEI NEW AREA, NANJING, CN-210047, CHINA

GRISEOFULVIN (1000001953)	CHIFENG PHARMACEUTICAL COMPANY LIMITED , 84 YIDONG STREET, CHIFENG, HONGSHAN DISTRICT, INNER MONGOLIA, CN-024 001, CHINA
SUCRALFATE (1000009411)	SNJ LABS PRIVATE LIMITED , PLOT NO 5-16, SURVEY NO. 137, AT & POST, PADAVALA, KOTDA SANGANI, RAJKOT, GUJARAT, IN-360024, INDIA
FLECAINIDE ACETATE (2000007515)	EMCURE PHARMACEUTICALS LIMITED , D-24 & D-24/1, MIDC, KURKUMBH, TALUK DAUND, PUNE, MAHARASHTRA, IN-413802, INDIA
LANSOPRAZOLE (1000007341)	NIFTY LABS PRIVATE LIMITED , PLOT NO 50-A,B, G&H, 64-A, B, C&D, 65-A, B, C&D, 66-A&B, 67-A&B, IDA KONDAPALLY, IBRAHIMPATNAM, MANDAL, NTR DISTRICT, ANDHRA PRADESH, IN-521 228, INDIA
ATENOLOL (1000009849)	IPCA LABORATORIES LIMITED , PLOT NO.H-4, MIDC, WALUJ, CHHATRAPATI SAMBHAJINAGAR, MAHARASHTRA, IN-431136, INDIA
SULFASALAZINE (3000009594)	VIRCHOW DRUGS LIMITED , SURVEY NO. 639, TEMPLE ROAD, BONTHAPALLY VILLAGE, GUMMADIDALA MANDAL, SANGAREDDY DISTRICT, TELANGANA, IN 502313, INDIA
LIDOCAINE HYDROCHLORIDE (2000014083)	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
BENZBROMARONE (1000003448)	IPCA LABORATORIES LIMITED , PLOT NOS. 4722, 4723, 4731 AND 4732, GIDC ESTATE, ANKLESHWAR DISTRICT, BHARUCH, IN-393002, INDIA
TOFACITINIB (1000018860)	MICRO LABORATORIES LIMITED , PLOT 43-45 KIADB, ANEKAL TALUK, BOMMASANDRA-JIGANI LINK ROAD, BENGALURU, KARNATAKA, IN-560105, INDIA
BETAMETHASONE DIPROPIONATE (2000008360)	SYMBIOTICA SPECIALITY INGREDIENTS SDN. BHD , NO. 518 JALAN WAJA 4, WAJA INDUSTRIAL ESTATE, KULIM, KEDAH, MY-09000, MALAYSIA
SERTRALINE HYDROCHLORIDE (2000008378)	HARIKA DRUGS PRIVATE LIMITED , SURVEY NO. 165/A & 165/E, GUMMADIDALA VILLAGE, MEDAK DISTRICT, TELANGANA, IN-500 038, INDIA
PROPRANOLOL (1000009764)	IPCA LABORATORIES LIMITED , P.O. SEJAVTA, RATLAM, MADHYA PRADESH, IN-457002, INDIA
BETAMETHASONE VALERATE (2000008358)	SANJIVANI PHARMA , D2/CH/102 GIDC INDUSTRIAL ESTATE, VAGRA, BHARUCH, GUJARAT, IN-392130, INDIA

ETHAMBUTOL (1000002667)	CADILA PHARMACEUTICALS LIMITED , PLOT NO. 294 GIDC INDUSTRIAL ESTATE, BHARUCH DISTRICT, ANKLESHWAR, GUJARAT, IN-393002, INDIA
HYDROQUINONE (1000008752)	MEDILUX LABORATORIES PRIVATE LIMITED , PLOT NO. 98-99, SECTOR-I, INDUSTRIAL AREA DHAR DISTRICT, PITHAMPUR, MADHYA PRADESH, IN-454 775, INDIA
SIMVASTATIN (1000009116)	SUN PHARMACEUTICAL INDUSTRIES LIMITED , VILLAGE TOANSA, PO RAIL MAJRA, DISTRICT NAWANSHAHAR, PUNJAB, IN-144 533, INDIA
METRONIDAZOLE (1000001131)	WUHAN WUYAO PHARMACEUTICAL CO. LIMITED , 18 WANGFEN ROAD, FUCHI TOWN, YANGXIN COUNTY, HUANGSHI CITY, HUBEI, CN-435 229, CHINA
PHENELZINE SULFATE (4000007420)	TYCHE INDUSTRIES LIMITED , 6/223, SARPAVARAM, KAKINADA, ANDHRA PRADESH, IN-533 005, INDIA
RIFAXIMIN (1000007585)	MSN LABORATORIES PRIVATE LIMITED , SURVEY NOS 317, 320, 321, 322, 323, 604 & 605, RUDRARAM VILLAGE, PATANCHERU MANDAL, SANGAREDDY DISTRICT, TELANGANA, IN-502329, INDIA
ISONIAZID (1000007745)	AMSAL CHEM PRIVATE LIMITED , A-1/ 401, 402, 403 G.I.D.C. INDUSTRIAL ESTATE, DISTRICT BHARUCH, ANKLESHWAR, GUJARAT, IN-393002, INDIA
LOPERAMIDE HYDROCHLORIDE (2000008494)	VASUDHA PHARMA CHEM LIMITED , UNIT I, PLOT NO. 39 A & B, PHASE I, INDUSTRIAL DEVELOPMENT AREA, JEEDIMETLA, HYDERABAD, TELANGANA, IN-500055, INDIA
BECLOMETASONE DIPROPIONATE (4000006191)	AVIK PHARMACEUTICAL LIMITED , A-1/7 AND A-1/8, PHASE-1, GUJARAT INDUSTRIAL DEVELOPMENT CORPORATION AREA, VALSAD DISTRICT, VAPI, GUJARAT, IN-396195, INDIA
OXETACAIN (3000004664)	SUN PHARMACEUTICAL INDUSTRIES LIMITED , SATHAMMAI VILLAGE, KARUNKUZHAI POST, MADHURANTHAGAM TALUK, KANCHEEPURAM DISTRICT, TAMIL NADU, IN-603303, INDIA
ENALAPRIL MALEATE (2000007672)	ZHEJIANG HUAHAI PHARMACEUTICAL COMPANY LIMITED , XUNQIAO, LINHAI, ZHEJIANG, CN-317024, CHINA
AZELAIC ACID (1000007411)	TYCHE INDUSTRIES LIMITED , 6/223, SARPAVARAM, KAKINADA, ANDHRA PRADESH, IN-533 005, INDIA

TRETINOIN (1000009303)

**CHONGQING HUAPONT SHENGCHEM PHARMACEUTICALS COMPANY
LIMITED**, NO.666 RONGJUN ROAD, NANJIN AVENUE, HECHUAN DISTRICT,
CHONGQING, CN-401520, CHINA