

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

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	05/06/2026

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
FINASTERIDE (1000007415)	HUNAN YUXIN PHARMACEUTICAL COMPANY LIMITED , LONGXUTANG, SHAOYANG, HUNAN, CN-422001, CHINA	
ATENOLOL (1000009849)	IPCA LABORATORIES LIMITED , PLOT NO.H-4, MIDC, WALUJ, CHHATRAPATI SAMBHAJINAGAR, MAHARASHTRA, IN-431136, INDIA	

HALOPERIDOL (1000001486)	RPG LIFE SCIENCES LIMITED , 25 MIDC LAND, THANE-BELAPUR ROAD, NAVI MUMBAI, MAHARASHTRA, IN-400703, INDIA
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
TINIDAZOLE (1000009326)	AARTI DRUGS LIMITED , PLOT NO. N-198, MIDC, TARAPUR, TALUKA PALGHAR, DISTRICT THANE, MAHARASHTRA, IN-401 506, INDIA
OMEPRAZOLE (1000009101)	LEE PHARMA LIMITED , SURVEY NO. 10/G-1, GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, IN 502319, INDIA
GRISEOFULVIN (1000001953)	CHIFENG PHARMACEUTICAL COMPANY LIMITED , 84 YIDONG STREET, CHIFENG, HONGSHAN DISTRICT, INNER MONGOLIA, CN-024 001, CHINA
SPIRONOLACTONE (1000009436)	TIANJIN JINJIN PHARMACEUTICAL COMPANY LIMITED , 8 JINGFU ROAD, INDUSTRIAL ZONE OF ZHANGJIAWO TOWN, XIQING DISTRICT, TIANJIN, CN- 300387, CHINA
BISACODYL (1000007386)	JPN PHARMA PRIVATE LIMITED , T-108/109, MIDC, TARAPUR, BOISAR, THANE DISTRICT, MAHARASHTRA, IN-401 506, INDIA
FLECAINIDE ACETATE (2000007515)	EMCURE PHARMACEUTICALS LIMITED , D-24 & D-24/1, MIDC, KURKUMBH, TALUK DAUND, PUNE, MAHARASHTRA, IN-413802, INDIA
AMIODARONE HYDROCHLORIDE (2000008524)	CTX LIFESCIENCES PRIVATE LIMITED , BLOCK NO. 251-252, SACHIN- MAGDALLA ROAD, GIDC, SACHIN, SURAT, GUJARAT, IN-394 230, INDIA
AZELAIC ACID (1000007411)	TYCHE INDUSTRIES LIMITED , 6/223, SARPAVARAM, KAKINADA, ANDHRA PRADESH, IN-533 005, INDIA
LEVAMISOLE HYDROCHLORIDE (2000006314)	NANJING WHITE WHALE PHARMA , NO. 29 FANGSHUIDONG ROAD, NANJING JIANBEI NEW AREA, NANJING, CN-210047, CHINA
PROBENECID (1000009786)	D K PHARMA CHEM PRIVATE LIMITED , F-32/W-7, MIDC BADLAPUR, MUMBAI, MAHARASHTRA, IN-421 503, INDIA
TELMISARTAN (1000008495)	CALYX CHEMICALS AND PHARMACEUTICALS LIMITED , N/102/91/90 MIDC, TARAPUR, BOISAR, PALGHAR DISTRICT, MAHARASHTRA, IN-401 506, INDIA

METRONIDAZOLE
(1000001131)

WUHAN WUYAO PHARMACEUTICAL CO. LIMITED, 18 WANGFEN ROAD,
FUCHI TOWN, YANGXIN COUNTY, HUANGSHI CITY, HUBEI, CN-435 229,
CHINA

TRETINOIN (1000009303)

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

METFORMIN
HYDROCHLORIDE
(2000008338)

AURO LABORATORIES LIMITED, NAVAPUR ROAD, K-56 MIDC, BOISAR,
DISTRICT TARAPUR, MAHARASHTRA, IND-401506, INDIA

OXETACAINE (3000004664)

SUN PHARMACEUTICAL INDUSTRIES LIMITED, SATHAMMAI VILLAGE,
KARUNKUZHAI POST, MADHURANTHAGAM TALUK, KANCHEEPURAM
DISTRICT, TAMIL NADU, IN-603303, INDIA

BENZBROMARONE
(1000003448)

IPCA LABORATORIES LIMITED, PLOT NOS. 4722, 4723, 4731 AND 4732,
GIDC ESTATE, ANKLESHWAR DISTRICT, BHARUCH, IN-393002, 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

CLOBETASOL PROPIONATE
(2000008014)

SYMBIOTICA SPECIALITY INGREDIENTS SDN. BHD, NO. 518 JALAN WAJA 4,
WAJA INDUSTRIAL ESTATE, KULIM, KEDAH, MY-09000, MALAYSIA

SULFAPYRIDINE
(3000017230)

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

CLOPIDOGREL BISULFATE
(4000011216)

PRAVEEN LABORATORIES PRIVATE LIMITED, BLOCK NO. 206, PALSANA
TALUKA, JOLWA VILLAGE, SURAT, GUJARAT, IN-394305, INDIA

TRANEXAMIC ACID
(1000009308)

AMI LIFESCIENCES PRIVATE LIMITED, BLOCK NO. 82/B, ECP ROAD, AT &
PO, KARAKHADI, TA. PADRA, BARODA, IN 391450, INDIA

SULFASALAZINE
(3000009594)

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

TOFACITINIB (1000018860)

MICRO LABORATORIES LIMITED, API DIVISION (ML-15) PLOT 43-45 KIADB,
ANEKAL TALUK, BOMMASANDRA-JIGANI LINK ROAD, BENGALURU,
KARNATAKA, IN-560105, INDIA

METHOXSALLEN
(1000007442)

SOLARA ACTIVE PHARMA SCIENCES LIMITED, 120 A & B, 36, 120P &121,
INDUSTRIAL AREA, BAIKAMPADY, NEW MANGALORE, KARNATAKA, IN-
575011, INDIA

ENALAPRIL MALEATE
(2000007672)

ZHEJIANG HUAHAI PHARMACEUTICAL COMPANY LIMITED, XUNQIAO,
LINHAI, ZHEJIANG, CN-317024, CHINA

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

MERCAPTOPURINE
MONOHYDRATE
(2000020211)

AARTI PHARMALABS LIMITED, UNIT IV - PLOT NO. E-50, 50/1 & 59/1 M.I.D.C,
TALUKA PALGHAR, TARAPUR, DISTRICT PALGHAR, MAHARASHTRA, IN-401
506, INDIA

EOSIN (1000005976)

JPN PHARMA PRIVATE LIMITED, T-108/109, MIDC, TARAPUR, BOISAR,
THANE DISTRICT, MAHARASHTRA, IN-401 506, 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

TACROLIMUS
MONOHYDRATE
(2000016490)

CONCORD BIOTECH LIMITED, 1482-1486 TRASAD ROAD, DHOLKA,
AHMEDABAD DISTRICT, GUJARAT, IN-382 225, INDIA

OXANDROLONE
(1000016028)

NURAY CHEMICALS PRIVATE LIMITED, GROUND FLOOR, PLOT NUMBER
111, SIDCO INDUSTRIAL ESTATE, KAKKALUR, THIRUVALLUR, TAMIL NADU,
IN-602003, INDIA

DITHRANOL (1000002937)

SUJALAM CHEMICALS, A-43 M.I.D.C., KURKUMBH, TAL, DAUND, DISTRICT
PUNE, IN-413802, INDIA

ACETAZOLAMIDE
(1000002240)

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

MONOBENZONE
(1000019033)

CHANGZHOU SUNLIGHT PHARMACEUTICAL COMPANY LIMITED, 216
YUNNAN WEST ROAD, BENNIU TOWN, XINBEI DISTRICT, CHANGZHOU
CITY, JIANGSU PROVINCE, CN 213134, CHINA

SIMVASTATIN (1000009116)

SUN PHARMACEUTICAL INDUSTRIES LIMITED, VILLAGE TOANSA, PO RAIL
MAJRA, DISTRICT NAWANSHAHAR, PUNJAB, IN-144 533, INDIA

AZATHIOPRINE (1000009761)	RPG LIFE SCIENCES LIMITED , 25 MIDC LAND, THANE-BELAPUR ROAD, NAVI MUMBAI, MAHARASHTRA, IN-400703, INDIA
PARACETAMOL (1000009609)	FARMSON PHARMACEUTICAL GUJARAT PRIVATE LIMITED , PLOT NO. 14 GIDC INDUSTRIAL ESTATE, NANDESARI, VADODARA DISTRICT, GUJARAT, IN-391340, INDIA
BECLOMETASONE DIPROPIONATE (4000006191)	AVIK PHARMACEUTICAL LIMITED , A-1/7 AND A-1/8, PHASE-1, GUJARAT INDUSTRIAL DEVELOPMENT CORPORATION AREA, VALSAD DISTRICT, VAPI, GUJURAT, IN-396195, INDIA
DILTIAZEM HYDROCHLORIDE (2000007763)	DIVI'S LABORATORIES LIMITED , UNIT 1, LINGOJIGUDEM VILLAGE, CHOUTUPPAL MANDAL, YADADRI BHUVANAGIRI DISTRICT, TELANGANA, IN-508252, INDIA
ETHAMBUTOL (1000002667)	CADILA PHARMACEUTICALS LIMITED , PLOT NO. 294 GIDC INDUSTRIAL ESTATE, BHARUCH DISTRICT, ANKLESHWAR, 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
PRAZOSIN HYDROCHLORIDE (2000007918)	NURAY CHEMICALS PRIVATE LIMITED , GROUND FLOOR, PLOT NUMBER 111, SIDCO INDUSTRIAL ESTATE, KAKKALUR, THIRUVALLUR, TAMIL NADU, IN-602003, INDIA
SULFADIAZINE SILVER (2000007397)	MACSEN DRUGS , F-261,263,263 RIICO INDUSTRIAL AREA, GUDLI, TEHSIL- MAVLI, UDAIPUR, RAJASTHAN, IN-313024, INDIA
NITAZOXANIDE (1000000749)	AZICO BIOPHORE INDIA PRIVATE LIMITED , PLOT NO. 40/A, JN PHARMACITY, PARAWADA MANDAL, ANAKAPALLI, ANDHRA PRADESH, IN- 531021, INDIA
HYDROQUINONE (1000008752)	MEDILUX LABORATORIES PRIVATE LIMITED , PLOT NO. 98-99, SECTOR-I, INDUSTRIAL AREA DHAR DISTRICT, PITHAMPUR, MADHYA PRADESH, IN- 454 775, INDIA
ZONISAMIDE (1000003230)	ENAL DRUGS PRIVATE LIMITED , D-33, 34 & 35, PHASE 1, IDA, JEEDIMETLA, HYDERABAD, IN-500055, INDIA
RAMIPRIL (1000009080)	MELODY HEALTHCARE PRIVATE LIMITED , PLOT NO. J-73, MIDC, DIST. PALGHAR, TARAPUR, MAHARASHTRA, IN-401506, INDIA

CLONIDINE HYDROCHLORIDE (2000008010)	ALEMBIC PHARMACEUTICALS LIMITED , UNIT I, P.O. TAJPURA, NEAR BASKA, TALUKA HALOL, PANCHMAHAL DISTRICT, PANELAV VILLAGE, GUJARAT, IN-389350, INDIA
AMLODIPINE BESILATE (2000015864)	IPCA LABORATORIES LIMITED , PLOT NO.H-4, MIDC, WALUJ, CHHATRAPATI SAMBAJINAGAR, MAHARASHTRA, IN-431136, INDIA
CHLOROTHIAZIDE (1000004605)	CTX LIFESCIENCES PRIVATE LIMITED , BLOCK NO. 251-252, SACHIN-MAGDALLA ROAD, GIDC, SACHIN, SURAT, GUJARAT, IN-394 230, INDIA
PRAZQUANTEL (1000015572)	SOLARA ACTIVE PHARMA SCIENCES LIMITED , 120 A & B, 36, 120P &121, INDUSTRIAL AREA, BAIKAMPADY, NEW MANGALORE, KARNATAKA, IN-575011, 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
FLUNARIZINE DIHYDROCHLORIDE (4000009677)	FLEMING LABORATORIES LIMITED , SURVEY NUMBER 270, NAWABPET VILLAGE, SIVAMPET MANDAL, MEDAK DISTRICT, TELANGANA, IN-502313, 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
NADOLOL (1000000391)	AZICO BIOPHORE INDIA PRIVATE LIMITED , PLOT NO. 40/A, JN PHARMACITY, PARAWADA MANDAL, ANAKAPALLI, ANDHRA PRADESH, IN-531021, INDIA
IVERMECTIN (1000001158)	BAJAJ HEALTHCARE LIMITED , UNIT II, BLOCK NO 588, SAVLI-KARACHIA ROAD, SAVLI, VANDODARA, GOTHADA, GUJARAT, IN-391776, INDIA
ORPHENADRINE CITRATE (2000008058)	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 DIPROPIONATE (2000008360)	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

PHENELZINE SULFATE (4000007420)	TYCHE INDUSTRIES LIMITED , 6/223, SARPAVARAM, KAKINADA, ANDHRA PRADESH, IN-533 005, INDIA
SODIUM BENZOATE (2000013061)	GANESH BENZOPLAST LIMITED , D-21/2/2 MIDC INDUSTRIAL AREA, TARAPUR, MAHARASHTRA, IN-401506, INDIA
METOLAZONE (1000001205)	AZICO BIOPHORE INDIA PRIVATE LIMITED , PLOT NO. 40/A, JN PHARMACITY, PARAWADA MANDAL, ANAKAPALLI, ANDHRA PRADESH, IN-531021, 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
CAPSAICIN (1000006807)	AUDI PHARMACEUTICALS PRIVATE LIMITED , D/9/B, 27TH CROSS STREET, MAHARAJANAGAR, TIRUNELVELI, TAMIL NADU, IN-627011, INDIA
SODIUM PHENYLBUTYRATE (2000005746)	SRI KRISHNA PHARMACEUTICALES LIMITED , UNIT III, SURVEY NO 57, GOLKONDA KALAN, RAIKUNTA VILLAGE, SHAMSHABAD MANDAL, TELANGANA, IN-501218, INDIA
TOPIRAMATE (1000002932)	MSN ORGANICS PRIVATE LIMITED , SURVEY NUMBER 224/A, BIBINAGAR MANDAL, YADADRI BHUVANAGIRI DISTRICT, BIBINAGAR VILLAGE, TELANGANA, IN-508126, 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
BETAMETHASONE VALERATE (2000008358)	SANJIVANI PHARMA , D2/CH/102 GIDC INDUSTRIAL ESTATE, VAGRA, BHARUCH, GUJARAT, IN-392130, INDIA
SUCRALFATE (1000009411)	SNJ LABS PRIVATE LIMITED , PLOT NO 5-16, SURVEY NO. 137, AT & POST, PADAVALA, KOTDA SANGANI, RAJKOT, GUJARAT, IN-360024, 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
SERTRALINE HYDROCHLORIDE (2000008378)	HARIKA DRUGS PRIVATE LIMITED , SURVEY NO. 165/A & 165/E, GUMMADIDALA VILLAGE, MEDAK DISTRICT, TELANGANA, IN-500 038, 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

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

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

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