

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 142 |
| 2. Name or corporate name of registrant | ACCORD-UK LIMITED |
| 3. Permanent or legal address of registrant | ACCORD-UK LIMITED, WHIDDON VALLEY, BARNSTAPLE,
EX32 8NS, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | ACCORD-UK LIMITED, WHIDDON VALLEY, BARNSTAPLE,
EX32 8NS, 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 | 02/06/2023 |

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

ACCORD-UK LIMITED, WHIDDON VALLEY, BARNSTAPLE, EX32 8NS, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance

3rd Country Manufacturer

3rd Country
Distributor

FOLIC ACID (1000001996)	SRI KRISHNA PHARMACEUTICALS LIMITED , UNIT III, SURVEY NO 57, GOLKONDA KALAN, RAIKUNTA VILLAGE, SHAMSHABAD MANDAL, TELANGANA, IN-501218, INDIA
	HEBEI JIHENG (GROUP) PHARMACEUTICAL , NO.1 WEIWU STREET, HENGSHUI INDUSTRIAL PARK, HENGSHUI CITY, HEBEI PROVINCE, CN- 053 000, CHINA
FUROSEMIDE (3000005943)	IPCA LABORATORIES LIMITED , P.O. SEJAVATA, RATLAM, MADHYA PRADESH, IN-457002, INDIA
THIAMINE HYDROCHLORIDE (4000010937)	JIANGXI TIANXIN PHARMACEUTICAL , LE'ANJIANG INDUSTRIAL ZONE, LEPING, ZIANGXI, CN-333300, CHINA
FLUOXETINE HYDROCHLORIDE (2000008390)	CADILA PHARMACEUTICALS LIMITED , PLOT NO. 294, GIDC INDUSTRIAL ESTATE, BHARUCH DISTRICT, ANKLESHWAR, GUJARAT, IN-393002, INDIA
DIPYRIDAMOLE (1000002962)	MYLAN LABORATORIES LIMITED , UNIT 9, PLOT NO. 5, ROAD NO 12, JAWAHARLAL NEHRU PHARMA CITY, TADI VILLAGE, PARAWADA MANDAL, VISAKHAPATNAM, ANDHRA PRADESH, IN-531019, INDIA
AMITRIPTYLINE HYDROCHLORIDE (2000008522)	R L FINE CHEM (KIADB) , PLOT NO IP-27-29, KIADB INDUSTRIAL AREA, 1ST PHASE, KUDUMALAKUNTE VILLAGE, GOWRIBIDANUR, CHIKKABALLAPUR DISTRICT, KARNATAKA, IN-561 208, INDIA
GABAPENTIN (1000007380)	HIKAL LIMITED , 82/A KIADB INDUSTRIAL AREA, JIGANI, ANEKAL TALUK, BANGALORE, KARNATAKA, IN-560 105, INDIA
DOXYCYCLINE HYCLATE (4000006937)	LIBERTY PHARMACEUTICALS , 22 YANGLI ROAD, HANJIANG INDUSTRIAL PARK, YANGZHOU, JIANGSU PROVINCE, CN-225 127, CHINA
HYDROCORTISONE MICRONISED (3000010308)	PHARMACIA & UPJOHN COMPANY , 7000 PORTAGE ROAD, KALAMAZOO, 49001, UNITED STATES
TRIMETHOPRIM (1000009283)	IPCA LABORATORIES LIMITED , P.O. SEJAVATA, RATLAM, MADHYA PRADESH, IN-457002, INDIA
AZITHROMYCIN DIHYDRATE (2000007794)	ZHJIEANG GUOBANG PHARMACEUTICAL CO. LIMITED , NO. 6 WEIWU ROAD, HANGZHOU GULF SHANGYU ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, SHANGYU, ZHEJIANG, CN-312 369, CHINA

	TIANJIN TIANYAO PHARMACEUTICALS CO. LIMITED , 19 XINYE 9TH STREET, WEST AREA OF TEDA, TIANJIN, CN-300 462, CHINA
PREDNISOLONE (1000009794)	HENAN LIHUA PHARMACEUTICAL CO LIMITED , MIDDLE OF HUANGHE STREET, ANYANG HI-TECH INDUSTRY DEVELOPMENT ZONE, ANYANG, HENAN, CN-455000, CHINA
FLECAINIDE ACETATE (2000007515)	MAPRIMED ARGENTINA , CORONEL PRUDENCIO MURGUIONDO 2011, BUENOS AIRES, AR-1440, ARGENTINA
	NEULAND LABORATORIES LIMITED , UNIT 1, BONTAPALLI VILLAGE, VEERABHADRASWAMY TEMPLE ROAD, JINNARAM MANDAL, MEDAK DISTRICT, TELANGANA, IN-502 313, INDIA
MIRTAZAPINE (1000003365)	ZHEJIANG LIAOYUAN PHARMACEUTICAL LIMITED , ZHEJIANG PROVINCIAL CHEMICAL AND MEDICAL RAW MATERIAL, BASE LINHAI ZONE, DUQIAO TOWN, LINHAI CITY, ZHEJIANG PROVINCE, CN-317 016, CHINA
CALCIUM GLUCONATE (2000011072)	ZHEJIANG RUIBANG LABORATORIES , NO 578 BINHAI TEN ROAD, ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, WENZHOU, ZHEJIANG PROVINCE, CN-325025, CHINA
DIGOXIN (1000003095)	DECCAN NUTRACEUTICALS PVT LIMITED (PART OF ALKALOIDS CORPORATION) , GAT NO. 1065, GOLEGAON ROAD, OFF ALANDI MARKAL ROAD, VILLAGE MARKAL, TALUKA KHED, PUNE, MAHARASHTRA, IN 412105, INDIA
LISINOPRIL DIHYDRATE (2000008500)	ZHEJIANG HUAHAI PHARMACEUTICAL CO. LIMITED , CHUANNAN NO 1 BRANCH FACTORY, COASTAL INDUSTRIAL ZONE, DUQIAO, LINHAI, ZHEJIANG PROVINCE, CN-317016, CHINA
NICOTINAMIDE (2000012339)	LONZA GUANGZHOU NANSHA LIMITED , 68 HUANGGE DADAOBEI, NANSHA DISTRICT, GUANGZHOU, GUANGDONG, CN-511 455, CHINA
PARACETAMOL COMPAP PVP3 (2000017331)	SPECGX LLC - GREENVILLE , 100 LOUIS LATZER DRIVE, GREENVILLE, 62246, UNITED STATES
SPIRONOLACTONE MICRONISED (2000018722)	TIANJIN JINJIN PHARMACEUTICAL CO. LIMITED , 8 JINGFU ROAD, ZHANGJIAWO TOWN INDUSTRIAL ZONE, XIQING DISTRICT ECONOMIC AND DEVELOPMENT AREA, ZHANGJIAWO, TIANJIN, CN-300380, CHINA
DAPSONE (1000003787)	ATUL LIMITED , NORTH SITE, PO ATUL, VALSAD, GUJARAT, IN-396020, INDIA

PROGESTERONE (1000009777)	ZHEJIANG SHENZHOU PHARMACEUTICAL NO.9 , NO. 9 HONGYUN ROAD, XIANDAI INDUSTRIAL ZONE, TAIZHOU, XIANJU, ZHEJIANG PROVINCE, CN-317300, CHINA
	PHARMACIA & UPJOHN COMPANY , 7000 PORTAGE ROAD, KALAMAZOO, 49001, UNITED STATES
NAPROXEN (1000009701)	DIVIS LABORATORIES LIMITED , UNIT 1, LINGOJIGUDEM VILLAGE, CHOUTUPPAL MANDAL, YADADRI BHUVANAGIRI DISTRICT, TELANGANA, IN-508252, INDIA
PHENOBARBITAL (1000014071)	HARMAN FINOCHEM LIMITED , PLOT NO. A-100, A-100-1, A-100-2, D-1, MIDC INDUSTRIAL AREA, SHENDRA, AURANGABAD, MAHARASHTRA, IN-431007, INDIA
ATORVASTATIN CALCIUM TRIHYDRATE (2000005733)	CENTRIENT PHARMACEUTICALS , BHAI MOHAN SINGH NAGAR, TOANSA, NAWANSHAHR, PUNJAB, IN-144 533, INDIA
ACICLOVIR (3000006349)	ZHEJIANG CHARIOTEER PHARMACEUTICAL CO. LIMITED , TONGYUANXI, DAZHAN, XIANJU, ZHEJIANG PROVINCE, CN-317 321, CHINA
	M/S VIRUPAKSHA ORGANICS LIMITED , SURVEY NO 10, GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, MEDAK DISTRICT, TELANGANA, IN-502 319, INDIA
TRAMADOL HYDROCHLORIDE (2000008034)	WANBURY LIMITED , K. ILLINDALAPARRU, IRAGAVARAM MANDAL, WEST GODAVARI DISTRICT, TANUKU, ANDHRA PRADESH, IN-534 217, INDIA
	EMMENNAR PHARMA PRIVATE LIMITED , PLOT NO. 15, JAWAHARLAL NEHRU PHARMA CITY, PARAWADA MANDA, VISAKAPATNAM DISTRICT, TADI VILLAGE, ANDHRA PRADESH, IN-531 019, INDIA
BENDROFLUMETHIAZIDE (3000006463)	IPCA LABORATORIES LIMITED , P.O. SEJAVTA, RATLAM, MADHYA PRADESH, Data Not Available, INDIA
	UNICHEM LABORATORIES LIMITED , PLOT NO 99, MIDC AREA, VILLAGE DHATAV-ROHA, RAIGAD, MAHARASHTRA, IN-402 116, INDIA
IMIPRAMINE HYDROCHLORIDE (2000007321)	TEVA API INDIA PRIVATE LIMITED , PLOT NOS Q1 TO Q4, INDUSTRIAL AREA, GHIRONGI, MALANPUR, BHIND, MADHYA PRADESH, IN-477 117, INDIA
CLOPIDOGREL BESILATE (2000013668)	CADILA HEALTHCARE LIMITED , PLOT NO. 26-29 AND 31, DABHASA UMARAYA ROAD, DABHASA, TAL PADRA, VADODARA, GUJARAT, IN-391440, INDIA

SALBUTAMOL SULPHATE (2000007742)	NEULAND LABORATORIES LIMITED , UNIT 1, SURVEY NO. 347, 473, 474, 490/2, VEERABHADRASWAMY TEMPLE ROAD, BONTAPALLI VILLAGE, GUMMADIDALA MANDAL, SANGAREDDY DISTRICT, TELANGANA, IN 502313, INDIA
	HEBEI JIHENG GROUP - SHENZHOU , SHENZHOU PLANT, XIJINGMING VILLAGE, DONGANZHUANG TOWNSHIP, SHENZHOU COUNTY, HENGSHUI CITY, HEBEI PROVINCE, CN-053800, CHINA
PARACETAMOL (1000009609)	HEBEI JIHENG (GROUP) PHARMACEUTICAL , NO.1 WEIWU STREET, HENGSHUI INDUSTRIAL PARK, HENGSHUI CITY, HEBEI PROVINCE, CN- 053 000, CHINA
	SPECGX LLC , RALEIGH PHARMACEUTICAL PLANT, 8801 CAPITAL BOULEVARD, RALEIGH, 27616, UNITED STATES
FENOFIBRATE (1000002301)	WAVELENGTH PHARMACEUTICALS , NEOT HOVAV ECO INDUSTRIAL PARK, P.O.BOX 3593, BEER SHEVA, IL-8413502, ISRAEL
GLICLAZIDE (1000001769)	ZHEJIANG JIUZHOU PHARMACEUTICAL , 99 WAISHA ROAD, JIAOJIANG, TAIZHOU CITY, ZHEJIANG, CN-318 000, CHINA
BUPRENORPHINE HYDROCHLORIDE (2000008277)	SPECGX LLC ST LOUIS , 3600 NORTH SECOND STREET, ST LOUIS, 63147, UNITED STATES
PROPRANOLOL HYDROCHLORIDE (2000007892)	SAI SUPREME CHEMICALS , PLOT NO.35, SIDCO INDUSTRIAL ESTATE, GUMMIDIPOONDI, THIRUVALLUR DISTRICT, TAMIL NADU, IN-601201, INDIA
	IPCA LABORATORIES LIMITED , P.O. SEJAVATA, RATLAM, MADHYA PRADESH, IN-457002, INDIA
HYDRALAZINE HYDROCHLORIDE (2000007339)	HETERO LABS LIMITED , UNIT I, SURVEY NO.10, I.D.A., GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, IN-502 319, INDIA
SULPHAMETHOXAZOLE (1000009392)	VIRCHOW LABORATORIES LIMITED , PLOT NO 4 TO 10 S.V.COOPERATIVE INDUSTRIAL ESTATE, I.D.A. JEEDIMETLA, HYDERABAD, IN 500055, INDIA
TETRACYCLINE HYDROCHLORIDE (2000007377)	NINGXIA QIYUAN PHARMACEUTICAL COMPANY LIMITED , NO 1 QIYUAN STEET, WANGYUAN INDUSTRIAL AREA, YINCHUAN, NINGXIA, CN- 750101, CHINA

PIROXICAM (1000009856)

ARCH PHARMALABS LIMITED, C-21/22 AND F-40, MIDC, PHASE II,
MANDAPA ROAD, SAGAON, THANE, MAHARASHTRA, IN-421204, INDIA

METHYLDOPA (1000000089)

ZHEJIANG WILD WIND PHARMACEUTICAL CO. LT, BEIJIANG
INDUSTRIAL ZONE, GESHAN TOWN, DONGYANG, ZHEJIANG, CN-
322105, CHINA

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