

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 46227
2. Name or corporate name of registrant	SAFIC-ALCAN UK LIMITED
3. Permanent or legal address of registrant	SAFIC-ALCAN UK LIMITED, 812 BIRCHWOOD BOULEVARD, BIRCHWOOD, WARRINGTON, WA3 7QZ, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	H.W. COATES LIMITED, MIDDLEWICH ROAD INDUSTRIAL ESTATE, BYLEY, MIDDLEWICH, CW10 9NT, UNITED KINGDOM SAFIC-ALCAN UK LIMITED, 812 BIRCHWOOD BOULEVARD, BIRCHWOOD, WARRINGTON, WA3 7QZ, 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	13/06/2025

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

H.W. COATES LIMITED, MIDDLEWICH ROAD INDUSTRIAL ESTATE, BYLEY, MIDDLEWICH, CW10 9NT, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance

HYDROQUINONE
(1000008752)

3rd Country Manufacturer

EASTMAN CHEMICAL COMPANY, 200 SOUTH WILCOX DRIVE, KINGSPORT,
37660, UNITED STATES

3rd Country Distributor

GUAIFENESIN (3000005625)	NOURYON FUNCTIONAL CHEMICALS B.V. , LISPINWEG 6, HERKENBOSCH, NL-6075 CE, NETHERLANDS
PARACETAMOL (1000009609)	FARMSON PHARMACEUTICAL GUJARAT PVT LIMITED , PLOT NO. 28-35 G.I.D.C. INDUSTRIAL ESTATE, NANDESARI, VADODARA DISTRICT, GUJARAT, IN-391340, INDIA
CYANOCOBALAMIN (4000010977)	HEBEI HUARONG PHARMACEUTICAL CO. LIMITED. , 50 NORTH 2ND RING ROAD EAST, CHANGAN QU, SHIJIAZHUANG, HEBEI SHENG, CN-050000, CHINA
SODIUM FEREDATE (4000007079)	NOURYON FUNCTIONAL CHEMICALS B.V. , LISPINWEG 6, HERKENBOSCH, NL-6075 CE, NETHERLANDS

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B	Distribution
	METFORMIN HYDROCHLORIDE (2000008338)
	BENAZEPRIL HYDROCHLORIDE (2000006111)
	HYDROQUINONE (1000008752)
	TACROLIMUS (1000002882)
	SIMETHICONE (1000009128)
	DEXAMETHASONE (1000003334)
	SUCRALFATE (1000009411)
	GUAIFENESIN (3000005625)
	NEOMYCIN SULPHATE (2000008175)
	FAMOTIDINE (1000002421)
	ENALAPRIL MALEATE (2000007672)
	PARACETAMOL (1000009609)
	EXEMESTANE (1000000183)
	AZITHROMYCIN DIHYDRATE (2000007794)
	DOXYCYCLINE MONOHYDRATE (2000007682)
	PREDNISOLONE ACETATE (2000007916)
	TRIMETHOPRIM (1000009283)
	N-ACETYLCYSTEINE (3000005344)
	ENROFLOXACIN (1000017859)
	METRONIDAZOLE BENZOATE (2000008258)
	CYANOCOBALAMIN (4000010977)
	CISAPRIDE (1000009097)
	SODIUM FEREDATE (4000007079)
	PRAZQUANTEL (1000015572)
	DOXYCYCLINE HYCLATE (4000006937)

Name and address of the site

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
SUCRALFATE (1000009411)	ZHEJIANG HAISEN PHARMACEUTICAL CO., LIMITED. , LIUSHI STREET, DONGYANG CITY, ZHEJIANG, CN-322104, CHINA	
PRAZIQUANTEL (1000015572)	HISUN PHARMACEUTICAL (NANTONG) CO., LTD. , NO. 18, 4TH HAIBIN ROAD, RUDONG COASTAL, ECONOMIC DEVELOPMENT ZONE, NANTONG, JIANGSU, CN-226407, CHINA	
ENROFLOXACIN (1000017859)	ZHEJIANG GUOBANG PHARMACEUTICAL CO. LTD. , NO. 6 WEIWU ROAD, HANGZHOU GULF SHANGYU ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, SHANGYU, ZHEJIANG, CN-312 369, CHINA	
AZITHROMYCIN DIHYDRATE (2000007794)	ZHEJIANG GUOBANG PHARMACEUTICAL CO. LTD. , NO. 6 WEIWU ROAD, HANGZHOU GULF SHANGYU ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, SHANGYU, ZHEJIANG, CN-312 369, CHINA	
CISAPRIDE (1000009097)	SHAOXING JINGXIN PHARMACEUTICAL CO., LIMITED. , NO 31 WEISAN ROAD, HANGZHOU BAY SHANGYU ECONOMIC AND TECHNICAL DEVELOPMENT AREA, SHANGYU, SHAOXING, ZHEJIANG PROVINCE, CN-312 369, CHINA	
DOXYCYCLINE HYCLATE (4000006937)	SHANDONG GUOBANG PHARMACEUTICAL CO., LTD. , NO. 02131 XIANGJIANGXIYI STREET, ADVANCED MANUFACTURING INDUSTRIAL PARK, BINHAI ECONOMIC DEVELOPMENT ZONE, WEIFANG, SHANDONG, CN-261108, CHINA	
ENALAPRIL MALEATE (2000007672)	ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD. , XUNQIAO, LINHAI CITY, ZHEJIANG PROVINCE, CN-317024, CHINA	
DOXYCYCLINE MONOHYDRATE (2000007682)	YANCHENG SUHAI PHARMACEUTICALS COMPANY LIMITED , HUAFENG INDUSTRIAL PARK, DAFENG PORT ECONOMIC ZONE, DAFENG DISTRICT, YANCHENG CITY, JIANGSU PROVINCE, CN-224100, CHINA	
METRONIDAZOLE BENZOATE (2000008258)	HUBEI HONGYUAN PHARMACEUTICAL TECHNOLOGY CO., LIMITED. , NO. 8, HONGYUAN ROAD, ECONOMIC DEVELOPMENT ZONE, LUOTIAN COUNTY, FENGSHAN TOWN, HUANGGANG CITY, HUBEI, CN-438 600, CHINA	

EXEMESTANE
(100000183)

SHANDONG ANHONG PHARMACEUTICAL CO., LIMITED, NO. 29 HUAYUAN STREET, LINHI COUNTY, DEZHOU CITY, SHANDONG PROVINCE, CN-251500, CHINA

N-ACETYLCYSTEINE
(3000005344)

WUHAN GRAND HOYO COMPANY LIMITED, ROOM 1, 6TH FLOOR, BUILDING 3, INTERNATIONAL ENTERPRISE CENTRE, NO. T1, GUANSHAN 2ND ROAD, EAST LAKE HIGH TECH DEVELOPMENT ZONE, WUHAN, HUBEI PROVINCE, CN-430070, CHINA

TACROLIMUS
(1000002882)

JOYANG LABORATORIES, NO. 9 NORTH HAIDOU ROAD, SHEYANG ECONOMIC DEVELOPMENT ZONE, YANCHENG, JIANGSU PROVINCE, CN 224300, CHINA

DEXAMETHASONE
(1000003334)

TIANJIN TIANYAO PHARMACEUTICALS CO LIMITED, 19 XINYE 9TH STREET, WEST AREA OF TIANJIN ECONOMIC TECHNOLOGICAL DEVELOPMENT AREA, TIANJIN, CN-300 462, CHINA

HYDROQUINONE
(1000008752)

EASTMAN CHEMICAL COMPANY, 200 SOUTH WILCOX DRIVE, KINGSPORT, 37660, UNITED STATES

SODIUM FEREDETATE
(4000007079)

NOURYON FUNCTIONAL CHEMICALS B.V., LISPINWEG 6, HERKENBOSCH, NL-6075 CE, NETHERLANDS

NEOMYCIN SULPHATE
(2000008175)

YICHANG SANXIA PHARMACEUTICAL COMPANY LIMITED, NO. 8 ZIYANG ROAD, DIAJUN DISTRICT, YICHANG, HUBEI, CN-443002, CHINA

METFORMIN
HYDROCHLORIDE
(2000008338)

SHOUGUANG FUKANG PHARMACEUTICAL CO. LTD, NORTH-EAST OF DONGWAIHUAN ROAD, DONGCHENG INDUSTRIAL AREA, SHOUGUANG, SHANDONG PROVINCE, CN-262700, CHINA

BENZAEPRI
L HYDROCHLORIDE
(2000006111)

ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., XUNQIAO, LINHAI CITY, ZHEJIANG PROVINCE, CN-317024, CHINA

TRIMETHOPRIM
(1000009283)

SHOUGUANG FUKANG PHARMACEUTICAL CO. LTD, NORTH-EAST OF DONGWAIHUAN ROAD, DONGCHENG INDUSTRIAL AREA, SHOUGUANG, SHANDONG PROVINCE, CN-262700, CHINA

GUAIFENESIN
(3000005625)

SYNTHOKEM LABS PVT LIMITED, PLOT NO 1911, B-5, INDUSTRIAL ESTATE, SANATHNAGAR, HYDERABAD, IN-500 018, INDIA

FAMOTIDINE
(1000002421)

ALEMBIC PHARMACEUTICALS LTD, VILLAGE PANELAV, PO TAJPURA, NEAR BASKA, TALUKA HALOL, PANCHMAHAL, GUJARAT, IN-389350, INDIA

CYANOCOBALAMIN
(4000010977)

HEBEI HUARONG PHARMACEUTICAL CO. LIMITED., 50 NORTH 2ND RING
ROAD EAST, CHANGAN QU, SHIJIAZHUANG, HEBEI SHENG, CN-050000,
CHINA

PREDNISOLONE
ACETATE (2000007916)

ZHEJIANG XIANJU PHARMACEUTICAL CO. LIMITED, NO. 1 XIANYAO ROAD,
XIANJU, ZHEJIANG, CN-317300, CHINA

PARACETAMOL
(1000009609)

FARMSON PHARMACEUTICAL GUJARAT PVT LIMITED, PLOT NO. 28-35
G.I.D.C. INDUSTRIAL ESTATE, NANDESARI, VADODARA DISTRICT, GUJARAT,
IN-391340, INDIA

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