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	27/05/2026

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

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

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
GUAIFENESIN (3000005625)	**NOURYON FUNCTIONAL CHEMICALS B.V.**, LISPINWEG 6, HERKENBOSCH, NL-6075 CE, NETHERLANDS	

MHRA-GMDP

HYDROQUINONE (1000008752)	**EASTMAN CHEMICAL COMPANY**, 200 SOUTH WILCOX DRIVE, KINGSPORT, 37660, UNITED STATES
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 FEREDETATE (4000007079)	**NOURYON FUNCTIONAL CHEMICALS B.V.**, LISPINWEG 6, HERKENBOSCH, NL-6075 CE, NETHERLANDS
TINIDAZOLE (1000009326)	**ZHEJIANG SUPOR PHARMACEUTICALS CO., LIMITED**, YUEDONG ROAD, PAOJIANG INDUSTRIAL ZONE, SHAOXING, ZHEJIANG, RC-312071, CHINA

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

AZITHROMYCIN DIHYDRATE (2000007794)

PREDNISOLONE ACETATE (2000007916)

GUAIFENESIN (3000005625)

HYDROQUINONE (1000008752)

SIMETHICONE (1000009128)

PARACETAMOL (1000009609)

ENALAPRIL MALEATE (2000007672)

PRAZIQUANTEL (1000015572)

CISAPRIDE (1000009097)

CYANOCOBALAMIN (4000010977)

METFORMIN HYDROCHLORIDE (2000008338)

FAMOTIDINE (1000002421)

NEOMYCIN SULPHATE (2000008175)

N-ACETYLCYSTEINE (3000005344)

TACROLIMUS (1000002882)

DOXYCYCLINE HYCLATE (4000006937)

SODIUM FEREDETATE (4000007079)

SUCRALFATE (1000009411)

TRIMETHOPRIM (1000009283)

TINIDAZOLE (1000009326)

ENROFLOXACIN (1000017859)

METRONIDAZOLE BENZOATE (2000008258)

DEXAMETHASONE (1000003334)

MHRA-GMDP MHRA MHRA-GMDP MHRA

EXEMESTANE (1000000183)

DOXYCYCLINE MONOHYDRATE (2000007682)

BENAZEPRIL HYDROCHLORIDE (2000006111)

Name and address of the site

SAFIC-ALCAN UK LIMITED, 812 BIRCHWOOD BOULEVARD, BIRCHWOOD, WARRINGTON, WA3 7QZ, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
FAMOTIDINE (1000002421)	**ALEMBIC PHARMACEUTICALS LTD**, VILLAGE PANELAV, PO TAJPURA, NEAR BASKA, TALUKA HALOL, PANCHMAHAL, GUJARAT, IN-389350, INDIA	
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	
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	
CYANOCOBALAMIN (4000010977)	**HEBEI HUARONG PHARMACEUTICAL CO. LIMITED.**, 50 NORTH 2ND RING ROAD EAST, CHANGAN QU, SHIJIAZHUANG, HEBEI SHENG, CN-050000, CHINA	
TRIMETHOPRIM (1000009283)	**SHOUGUANG FUKANG PHARMACEUTICAL CO. LTD**, NORTH-EAST OF DONGWAIHUAN ROAD, DONGCHENG INDUSTRIAL AREA, SHOUGUANG, SHANDONG PROVINCE, CN-262700, CHINA	
PRAZIQUANTEL (1000015572)	**HISUN PHARMACEUTICAL (NANTONG) CO., LTD.**, NO. 18, 4TH HAIBIN ROAD, RUDONG COASTAL, ECONOMIC DEVELOPMENT ZONE, NANTONG, JIANGSU, CN-226407, 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	
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	

MHRA-GMDP MHRA

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
METFORMIN HYDROCHLORIDE (2000008338)	**SHOUGUANG FUKANG PHARMACEUTICAL CO. LTD**, NORTH-EAST OF DONGWAIHUAN ROAD, DONGCHENG INDUSTRIAL AREA, SHOUGUANG, SHANDONG PROVINCE, CN-262700, 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
HYDROQUINONE (1000008752)	**EASTMAN CHEMICAL COMPANY**, 200 SOUTH WILCOX DRIVE, KINGSPORT, 37660, UNITED STATES
PREDNISOLONE ACETATE (2000007916)	**ZHEJIANG XIANJU PHARMACEUTICAL CO. LIMITED**, NO. 1 XIANYAO ROAD, XIANJU, ZHEJIANG PROVINCE, CN-317300, 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
EXEMESTANE (1000000183)	**SHANDONG ANHONG PHARMACEUTICAL CO., LIMITED**, NO. 29 HUAYUAN STREET, LINHI COUNTY, DEZHOU CITY, SHANDONG PROVINCE, CN-251500, 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
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
TINIDAZOLE (1000009326)	**ZHEJIANG SUPOR PHARMACEUTICALS CO., LIMITED**, YUEDONG ROAD, PAOJIANG INDUSTRIAL ZONE, SHAOXING, ZHEJIANG, RC-312071, CHINA
ENALAPRIL MALEATE (2000007672)	**ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.**, XUNQIAO, LINHAI CITY, ZHEJIANG PROVINCE, CN-317024, CHINA

MHRA-GMDP MHRA

PARACETAMOL (1000009609)	**FARMSON PHARMACEUTICAL GUJARAT PVT LIMITED**, PLOT NO. 28-35 G.I.D.C. INDUSTRIAL ESTATE, NANDESARI, VADODARA DISTRICT, GUJARAT, IN-391340, INDIA
GUAIFENESIN (3000005625)	**SYNTHOKEM LABS PVT LIMITED**, PLOT NO 1911, B-5, INDUSTRIAL ESTATE, SANATHNAGAR, HYDERABAD, IN-500 018, INDIA
TACROLIMUS (1000002882)	**JOYANG LABORATORIES**, NO. 9 NORTH HAIDOU ROAD, SHEYANG ECONOMIC DEVELOPMENT ZONE, YANCHENG, JIANGSU PROVINCE, CN 224300, CHINA
SUCRALFATE (1000009411)	**ZHEJIANG HAISEN PHARMACEUTICAL CO., LIMITED.**, LIUSHI STREET, DONGYANG CITY, ZHEJIANG, CN-322104, CHINA
BENAZEPRIL HYDROCHLORIDE (2000006111)	**ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.**, XUNQIAO, LINHAI CITY, ZHEJIANG PROVINCE, CN-317024, CHINA

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

FAMOTIDINE (1000002421)

AZITHROMYCIN DIHYDRATE (2000007794)

ENROFLOXACIN (1000017859)

CYANOCOBALAMIN (4000010977)

TRIMETHOPRIM (1000009283)

PRAZIQUANTEL (1000015572)

DOXYCYCLINE MONOHYDRATE (2000007682)

SODIUM FEREDETATE (4000007079)

NEOMYCIN SULPHATE (2000008175)

N-ACETYLCYSTEINE (3000005344)

METFORMIN HYDROCHLORIDE (2000008338)

CISAPRIDE (1000009097)

HYDROQUINONE (1000008752)

PREDNISOLONE ACETATE (2000007916)

DOXYCYCLINE HYCLATE (4000006937)

EXEMESTANE (1000000183)

DEXAMETHASONE (1000003334)

METRONIDAZOLE BENZOATE (2000008258)

TINIDAZOLE (1000009326)

ENALAPRIL MALEATE (2000007672)

PARACETAMOL (1000009609)

GUAIFENESIN (3000005625)

TACROLIMUS (1000002882)

MHRA-GMDP MHRA

SUCRALFATE (1000009411)

SIMETHICONE (1000009128)

BENAZEPRIL HYDROCHLORIDE (2000006111)

MHRA-GMDP

MHRA-GMDP