

# 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	26/05/2023

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

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

### 2. IMPORTATION AND DISTRIBUTION OPERATIONS

#### A Importation

##### Active Substance

PARACETAMOL  
(1000009609)

##### 3rd Country Manufacturer

**FARMSON PHARMACEUTICAL GUJARAT PVT LIMITED**, 28-35 GIDC  
INDUSTRIAL ESTATE, NANDESARI, VADODARA, GUJARAT, IN-391 340,  
INDIA

##### 3rd Country Distributor

GUAIFENESIN  
(3000005625)

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

HYDROQUINONE  
(1000008752)

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

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

- PARACETAMOL (1000009609)
- TACROLIMUS (1000002882)
- GUAIFENESIN (3000005625)
- ENROFLOXACIN (1000017859)
- SIMETHICONE (1000009128)
- HYDROQUINONE (1000008752)
- ENALAPRIL MALEATE (2000007672)
- AZITHROMYCIN DIHYDRATE (2000007794)
- TRIMETHOPRIM (1000009283)
- FAMOTIDINE (1000002421)
- CYANOCOBALAMIN (4000010977)
- BENAZEPRIL HYDROCHLORIDE (2000006111)
- SODIUM FEREDATE (4000007079)
- PRAZIQUANTEL (1000015572)
- METFORMIN HYDROCHLORIDE (2000008338)

### 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
HYDROQUINONE (1000008752)	<b>EASTMAN CHEMICAL COMPANY</b> , 200 SOUTH WILCOX DRIVE, KINGSPORT, 37660, UNITED STATES	

GUAIFENESIN (3000005625)	<b>SYNTHOKEM LABS PVT LIMITED</b> , PLOT NO 1911, B-5, INDUSTRIAL ESTATE, SANATHNAGAR, HYDERABAD, IN-500 018, INDIA
AZITHROMYCIN DIHYDRATE (2000007794)	<b>ZHEJIANG GUOBANG PHARMACEUTICAL CO. LTD.</b> , NO. 6 WEIWU ROAD, HANGZHOU GULF SHANGYU ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, SHANGYU, ZHEJIANG, CN-312 369, CHINA
ENALAPRIL MALEATE (2000007672)	<b>ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.</b> , XUNQIAO, LINHAI CITY, ZHEJIANG PROVINCE, CN-317024, CHINA
PRAZQUANTEL (1000015572)	<b>HISUN PHARMACEUTICAL (NANTONG) CO., LTD.</b> , NO. 18, 4TH HAIBIN ROAD, RUDONG COASTAL, ECONOMIC DEVELOPMENT ZONE, NANTONG, JIANGSU, CN-226407, CHINA
CYANOCOBALAMIN (4000010977)	<b>HEBEI HUARONG PHARMACEUTICAL CO. LIMITED.</b> , 50 NORTH 2ND RING ROAD EAST, CHANGAN QU, SHIJIAZHUANG, HEBEI SHENG, CN-050000, CHINA
FAMOTIDINE (1000002421)	<b>ALEMBIC PHARMACEUTICALS LTD</b> , VILLAGE PANELAV, PO TAJPURA, NEAR BASKA, TALUKA HALOL, PANCHMAHAL, GUJARAT, IN-389350, INDIA
ENROFLOXACIN (1000017859)	<b>ZHEJIANG GUOBANG PHARMACEUTICAL CO. LTD.</b> , NO. 6 WEIWU ROAD, HANGZHOU GULF SHANGYU ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, SHANGYU, ZHEJIANG, CN-312 369, CHINA
SODIUM FEREDETATE (4000007079)	<b>NOURYON FUNCTIONAL CHEMICALS B.V.</b> , LISPINWEG 6, HERKENBOSCH, NL-6075 CE, NETHERLANDS
BENAZEPRIL HYDROCHLORIDE (2000006111)	<b>ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.</b> , XUNQIAO, LINHAI CITY, ZHEJIANG PROVINCE, CN-317024, CHINA
TRIMETHOPRIM (1000009283)	<b>SHOUGUANG FUKANG PHARMACEUTICAL CO. LTD</b> , NORTH-EAST OF DONGWAIHUAN ROAD, DONGCHENG INDUSTRIAL AREA, SHOUGUANG, SHANDONG PROVINCE, CN-262700, CHINA
PARACETAMOL (1000009609)	<b>FARMSON PHARMACEUTICAL GUJARAT PVT LIMITED</b> , 28-35 GIDC INDUSTRIAL ESTATE, NANDESARI, VADODARA, GUJARAT, IN-391 340, INDIA
TACROLIMUS (1000002882)	<b>JOYANG LABORATORIES</b> , NO. 9 NORTH HAIDOU ROAD, SHEYANG ECONOMIC DEVELOPMENT ZONE, YANCHENG, JIANGSU PROVINCE, CN 224300, CHINA

METFORMIN  
HYDROCHLORIDE  
(2000008338)

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

## 2. IMPORTATION AND DISTRIBUTION OPERATIONS

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