

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 10696 |
| 2. Name or corporate name of registrant | ALFA CHEMICALS LIMITED |
| 3. Permanent or legal address of registrant | ALFA CHEMICALS LIMITED, ARC HOUSE, TERRACE ROAD SOUTH, BINFIELD, BRACKNELL, RG42 4PZ, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | ALFA CHEMICALS LIMITED, ARC HOUSE, TERRACE ROAD SOUTH, BINFIELD, BRACKNELL, RG42 4PZ, 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 | 04/05/2023 |

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

ALFA CHEMICALS LIMITED, ARC HOUSE, TERRACE ROAD SOUTH, BINFIELD, BRACKNELL, RG42 4PZ, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

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Active Substance

3rd Country Manufacturer

3rd Country Distributor

EPINEPHRINE (1000009945)

SYN-TECH CHEMICAL & PHARMACEUTICAL COMPANY LIMITED, NO.168 KAI YUAN ROAD, HSIN YING DISTRICT, TAINAN CITY, TW-73055, TAIWAN

DIGOXIN (1000003095)

DECCAN NUTRACEUTICALS PRIVATE LIMITED, GAT NO. 1065, GOLEGAON ROAD, OFF ALANDI MARKAL ROAD, VILLAGE MARKAL, TALUKA KHED, PUNE, MAHARASHTRA, IN 412105, INDIA

HYOSCINE
HYDROBROMIDE
(2000007323)

ALKALOIDS PRIVATE LIMITED, 25/3, MEDCHAL, RANGA REDDY DISTRICT,
GUNDLAPOCHAMPALLY, TELANGANA, IN-500 100, INDIA

EPINEPHRINE HYDROGEN
TARTRATE (4000014421)

SYN-TECH CHEMICAL & PHARMACEUTICAL COMPANY LIMITED, NO.168
KAI YUAN ROAD, HSIN YING DISTRICT, TAINAN CITY, TW-73055, TAIWAN

BELLADONNA EXTRACT
(2000008374)

HINDUSTAN PHARMACEUTICALS, KOT MIT SINGH, TARN TARAN ROAD,
AMRITSAR, PUNJAB, IN 143002, INDIA

HYOSCINE BUTYLBROMIDE
(2000007324)

ALKALOIDS PRIVATE LIMITED, 25/3, MEDCHAL, RANGA REDDY DISTRICT,
GUNDLAPOCHAMPALLY, TELANGANA, IN-500 100, INDIA

2. IMPORTATION AND DISTRIBUTION OPERATIONS

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Distribution

EPINEPHRINE (1000009945)

DIGOXIN (1000003095)

HYOSCINE HYDROBROMIDE (2000007323)

DOCETAXEL (1000003303)

CHLORHEXIDINE HYDROCHLORIDE (2000008100)

IRON SULPHATE (2000012033)

EPINEPHRINE HYDROGEN TARTRATE (4000014421)

COLCHICINE (1000003882)

IRON (II) SULFATE HEPTAHYDRATE (4000015084)

BELLADONNA EXTRACT (2000008374)

PACLITAXEL (1000007369)

SODIUM CHLORIDE (1000009536)

HYOSCINE BUTYLBROMIDE (2000007324)