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

2. Name or corporate name of registrant

3. Permanent or legal address of registrant

4. Address(es) of site(s) where registered activities take place

5. National legal basis of registration

UK API 10696

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

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

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

7. Date

03/05/2024

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

A Importation

Active Substance

3rd Country Manufacturer

DIGOXIN (1000003095)

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

3rd Country

Distributor

	KETOPROFEN (1000008346)	ANLON HEALTHCARE PVT. LIMITED, SURVEY NO. 36/2 P2,NEAR BHARUDI TOLL PLAZA, GONDAL ROAD NH 27, PIPALIYA (SADAK), TAL. GONDAL, DISTRICT RAJKOT, GUJARAT, IN-360311, INDIA
	HYOSCINE BUTYLBROMIDE (2000007324)	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
	HYOSCINE HYDROBROMIDE (2000007323)	ALKALOIDS PRIVATE LIMITED, 25/3, MEDCHAL, RANGA REDDY DISTRICT, GUNDLAPOCHAMPALLY, TELANGANA, IN-500 100, INDIA
	EPINEPHRINE (1000009945)	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
2. IMPORTATION AND DISTRIBUTION OPERATIONS		
В	Distribution	
	DIGOXIN (1000003095)	
	KETOPROFEN (1000008346)	
	IRON (II) SULFATE HEPTAHYDRATE (4000015084)	
	HYOSCINE BUTYLBROMIDE (2000007324)	
	CHLORHEXIDINE HYDROCHLORIDE (2000008100)	
	IRON SULPHATE (2000012033)	
	EPINEPHRINE HYDROGEN TARTRATE (4000014421)	
		3ROMIDE (2000007323)
	EPINEPHRINE (1000009945) BELLADONNA EXTRACT (2000008374)	
	.2	A.