

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 123
2. Name or corporate name of registrant	DALES PHARMACEUTICALS LIMITED
3. Permanent or legal address of registrant	DALES PHARMACEUTICALS LIMITED, SNAYGILL INDUSTRIAL ESTATE, KEIGHLEY ROAD, SKIPTON, BD23 2RW, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	DALES PHARMACEUTICALS LIMITED, SNAYGILL INDUSTRIAL ESTATE, KEIGHLEY ROAD, SKIPTON, BD23 2RW, 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	05/02/2014

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

DALES PHARMACEUTICALS LIMITED, SNAYGILL INDUSTRIAL ESTATE, KEIGHLEY ROAD, SKIPTON, BD23 2RW, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance

MEFENAMIC ACID
(1000000109)

3rd Country Manufacturer

DONGBANG FUTURE TECHNIQUE & LIFE CO.LTD, 904-5 SANGSIN-RI, HYANGNAM-MYUN, HWASUNG-CITY, KYUNGKI-DO, Data Not Available, SOUTH KOREA

YUNG ZIP CHEMICAL INDUSTRY COMPANY LIMITED, 59 YU SHIH ROAD, YOUTH INDUSTRIAL DISTRICT, TACHIA, TW-43767, TAIWAN

3rd Country Distributor

DEXAMPHEMINE
SULPHATE (2000007842)

CAMBREX CHARLES CITY INCORPORATED, 1205 ELEVENTH STREET,
CHARLES CITY, 50616, UNITED STATES

SODIUM FEREDATE
(4000007079)

SAI ADVANTIUM PHARMA LIMITED, UNIT IV PLOT NO 80-A, 80-B, 81-A
& 82, KOLHARE INDUSTRIAL AREA, BIDAR, KARNATAKA, IN-585403,
INDIA

MIDAZOLAM (1000000928)

LAKE CHEMICALS PRIVATE LIMITED, 5TH FLOOR LAKSHMI NARAYAN
COMPLEX, 10/1 PALACE ROAD, BENGALURU, KARNATAKA, IN-560052,
INDIA

TEMAZEPAM (1000009363)

CHEMAGIS LIMITED, PO BOX 3593, RAMAT HOVAV INDUSTRIAL AREA,
BEER SHEVA, IL-84135, ISRAEL

INOSITOL (1000008613)

CENTAUR PHARMACEUTICALS PRIVATE LIMITED, CENTAUR HOUSE,
NEAR GRAND HYATT, SHANTI NAGAR, VAKOLA, SANTACRUZ,
MUMBAI, IN-400055, INDIA

GRISEOFULVIN (1000001953)

TSUNO RICE FINE CHEMICALS COMPANY LIMITED, 2283
CHONOMACHI, KATSURAGI-CHO, ITO-GUN, WAKAYAMA, JP-649 7149,
JAPAN

ACETOMENAPHTHONE
(2000014020)

CHIFENG PHARMACEUTICAL COMPANY LIMITED, 84 YIDONG
STREET, CHIFENG, HONGSHAN DISTRICT, INNER MONGOLIA, CN-024
001, CHINA

MIDORI KAGAKU CO LIMITED, 2-27-8 MINAMI IKEBUKURO, TOSHIMA-
KU, TOKYO, JP-171-0022, JAPAN

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

TRILOSTANE MICRONISED (3000017510)