

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 12063 |
| 2. Name or corporate name of registrant | WRAFTON LABORATORIES LIMITED |
| 3. Permanent or legal address of registrant | WRAFTON LABORATORIES LIMITED, EXETER ROAD, WRAFTON,
BRAUNTON, EX33 2DL, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | WRAFTON LABORATORIES LIMITED, EXETER ROAD, WRAFTON,
BRAUNTON, EX33 2DL, 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 | 18/10/2024 |

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

WRAFTON LABORATORIES LIMITED, EXETER ROAD, WRAFTON, BRAUNTON, EX33 2DL, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance

3rd Country Manufacturer

3rd Country
Distributor

PHENYLEPHRINE HYDROCHLORIDE (2000008067)	DIVIS LABORATORIES LIMITED , LINGOJIGUDEM VILLAGE, CHOUTUPPAL MANDAL, NALGONDA DISTRICT, ANDHRA PRADESH, IND-508 252, INDIA
	MALLADI DRUGS & PHARMACEUTICALS LIMITED , UNIT 3, 7B AND 7C, SIPCOT INDUSTRIAL COMPLEX, RANIPET, RANIPET, TAMIL NADU, IN- 632403, INDIA
	MEGHMANI LLP , PLOT NO. CH-3, G.I.D.C. ESTATE, TA. VAGRA, DISTRICT BHARUCH, DAHEJ, GUJARAT, IN-392130, INDIA
	SPECGX LLC , 100 LOUIS LATZER DRIVE, GREENVILLE, 62246, UNITED STATES
PARACETAMOL (1000009609)	MALLINCKRODT INCORPORATION , 8801 NORTH BOULEVARD, RALEIGH, 27616-3198, UNITED STATES
	ANQIU LU'AN PHARMACEUTICAL COMPANY LIMITED , 35 WEIXU NORTH ROAD, ANQIU CITY, SHANDONG PROVINCE, CN-262 100, CHINA
IBUPROFEN LYSINE (2000011938)	SOLARA ACTIVE PHARMA SCIENCES LIMITED , RS NO. 33 & 34, MATHUR ROAD, PERIYAKALAPET, PUDUCHERRY, IN 605014, INDIA
NICOTINE POLACRILEX (2000006474)	CAMBREX CHARLES CITY INCORPORATION , 1205 ELEVENTH STREET, CHARLES CITY, 50616, UNITED STATES
	WAVELENGTH PHARMACEUTICALS LIMITED , NEOT HOVAV ECO INDUSTRIAL PARK, P.O.BOX 3593, BEER SHEVA, I-8413502, ISRAEL
CETIRIZINE HYDROCHLORIDE (2000008377)	GLOCHEM INDUSTRIES PRIVATE LIMITED , SURVEY NO. 174-176, I.D.A. BOLLARAM, SANGAREDDY DISTRICT, HYDERABAD, TELANGANA, IN- 502325, INDIA