

# 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,<br>BRAUNTON, EX33 2DL, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place   | WRAFTON LABORATORIES LIMITED, EXETER ROAD, WRAFTON,<br>BRAUNTON, EX33 2DL, UNITED KINGDOM |
| 5. National legal basis of registration  | Regulation 327 of The Human Medicines Regulations 2012 (SI<br>2012/1916)                  |
| 6. Name of responsible officer of the competent authority of<br>the member state validating the registration | Confidential  |
| 7. Date  | 24/04/2023  |

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

**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

**ANQIU LU'AN PHARMACEUTICAL COMPANY LIMITED**, 35 WEIXU  
NORTH ROAD, ANQIU CITY, SHANDONG PROVINCE, CN-262 100,  
CHINA

PARACETAMOL (1000009609) **SPECGX LLC**, 100 LOUIS LATZER DRIVE, GREENVILLE, 62246, UNITED  
STATES

**MALLINCKRODT INCORPORATION**, 8801 NORTH BOULEVARD,  
RALEIGH, 27616-3198, UNITED STATES

CETIRIZINE HYDROCHLORIDE **WAVELENGTH PHARMACEUTICALS LIMITED**, NEOT HOVAV ECO  
(2000008377) INDUSTRIAL PARK, P.O.BOX 3593, BEER SHEVA, I-8413502, ISRAEL

PHENYLEPHRINE **DIVIS LABORATORIES LIMITED**, LINGOJIGUDEM VILLAGE,  
HYDROCHLORIDE CHOUTUPPAL MANDAL, NALGONDA DISTRICT, ANDHRA PRADESH,  
(2000008067) IND-508 252, INDIA

NICOTINE POLACRILEX **CAMBREX CHARLES CITY INCORPORATION**, 1205 ELEVENTH  
(2000006474) STREET, CHARLES CITY, 50616, UNITED STATES