

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 12862
2. Name or corporate name of registrant	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED
3. Permanent or legal address of registrant	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED, D6 BUILDING, THANE ROAD, NOTTINGHAM, NG90 6BH, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED, NOTTINGHAM SITE, THANE ROAD, NOTTINGHAM, NG90 2DB, 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	28/02/2024

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

RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED, NOTTINGHAM SITE, THANE ROAD, NOTTINGHAM, NG90 2DB,
UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance

PHENYLEPHRINE
HYDROCHLORIDE
(2000008067)

3rd Country Manufacturer

MALLADI, UNIT 3, 7B AND 7C, SIPCOT INDUSTRIAL COMPLEX, RANIPET,
RANIPET, TAMIL NADU, IN-632403, INDIA

3rd Country Distributor

MENTHOL (1000001243)

ANHUI FENGLE PERFUME CO LIMITED, 1 TIANHU ROAD, HIGH-TECH INDUSTRIAL DEVELOPMENT ZONE, HEFEI, ANHUI, CN-230088, CHINA

SPECGX LLC, 100 LOUIS LATZER DRIVE, GREENVILLE, 62246, UNITED STATES

PARACETAMOL (1000009609)

SPECGX LLC, RALEIGH PHARMACEUTICAL PLANT, 8801 CAPITAL BOULEVARD, RALEIGH, 27616, UNITED STATES

ANQUI LU'AN PHARMACEUTICAL CO LIMITED, XIAO HE YA, NORTH PART OF THE ANQIU CITY, ANQIU, SHANDONG PROVINCE, CN-262100, CHINA

AMYLMETACRESOL
(1000000573)

BIOXERA, PLOT NO. N-57, M.I.D.C., ADDITIONAL AMBERNATH, AMBERNATH (EAST), THANE DISTRICT, MUMBAI, MAHARASHTRA, IN 421501, INDIA

BASF CORPORATION, HIGHWAY 77 SOUTH, BISHOP, 78343, UNITED STATES

IBUPROFEN (1000008918)

IOL CHEMICALS AND PHARMACEUTICALS LIMITED, MANSA ROAD (TRIDENT COMPLEX), DISTRICT BARNALA, FATEHGARH CHANNA VILLAGE, PUNJAB, IN-148101, INDIA

SOLARA ACTIVE PHARMA SCIENCES, RS NO. 33 & 34, MATHUR ROAD, PERIYAKALAPET, PUDUCHERRY, IN 605014, INDIA

CETYLPYRIDINIUM
(1000006275)

VERTELLUS HEALTH AND SPECIALITY PRODUCTS LLC, 215 NORTH CENTENNIAL STREET, ZEELAND, 49464-1309, UNITED STATES

CALCIUM CARBONATE D/C
(4000003925)

SUDEEP PHARMA, 129/1/A, G.I.D.C. ESTATE, NANDESARI, VADODARA, GUJARAT, IN 391340, INDIA

BENZOCAINE (1000009160)

CHANGZHOU SUNLIGHT, 216 YUNNAN WEST ROAD, BENNIU TOWN, XINBEI DISTRICT, CHANGZHOU CITY, JIANGSU PROVINCE, CN 213134, CHINA

HAMAMELIS WATER
(2000007408)

AMERICAN DISTILLING AND MANUFACTURING GROUP, 31 EAST HIGH STREET, EAST HAMPTON, 06424, UNITED STATES

IBUPROFEN SODIUM (2000011939)	SOLARA ACTIVE PHARMA SCIENCES , A1/B SIPCOT INDUSTRIAL COMPLEX, KUDIKADU, CUDDALORE, TAMIL NADU, IN-607005, INDIA SOLARA ACTIVE PHARMA SCIENCES , RS NO. 33 & 34, MATHUR ROAD, PERIYAKALAPET, PUDUCHERRY, IN 605014, INDIA IOL CHEMICALS AND PHARMACEUTICALS LIMITED , MANSA ROAD (TRIDENT COMPLEX), DISTRICT BARNALA, FATEHGARH CHANNA VILLAGE, PUNJAB, IN-148101, INDIA BASF , HIGHWAY 77 SOUTH, BISHOP, 78343, UNITED STATES
2,4-DICHLOROBENZYL ALCOHOL (3000009479)	BIOXERA , PLOT NO. N-57, M.I.D.C., ADDITIONAL AMBERNATH, AMBERNATH (EAST), THANE DISTRICT, MUMBAI, MAHARASHTRA, IN 421501, INDIA
PSEUDOEPHEDRINE HYDROCHLORIDE (2000007829)	EMBIO LIMITED , PLOT NO E21-22, MIDC INDUSTRIAL ESTATE, RAIGAD DISTRICT, MAHAD, MAHARASHTRA, IN-402309, INDIA MALLADI , UNIT 3, 7B AND 7C, SIPCOT INDUSTRIAL COMPLEX, RANIPET, RANIPET, TAMIL NADU, IN-632403, INDIA
FLURBIPROFEN (1000002036)	SUN PHARMACEUTICAL INDUSTRIES LIMITED. , A7/A8 MIDC INDUSTRIAL AREA, AHMEDNAGAR, MAHARASHTRA, IN-414111, INDIA HY-GRO CHEMICALS PHARMTEK PRIVATE LIMITED. , PLOT NO. 174, PROGRESSIVE INDUSTRIAL SOCIETY, I.D.A. BOLLARAM, BOLLARAM VILLAGE, JINNARAM Mandal, SANGAREDDY DISTRICT, TELANGANA, IN 502325, INDIA