

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 43457
2. Name or corporate name of registrant	SABAL HEALTH AND PHARMA LIMITED
3. Permanent or legal address of registrant	SABAL HEALTH AND PHARMA LIMITED, LAUNCHPAD, AIRPORT BUSINESS PARK, CHERRY ORCHARD WAY, ROCHFORD, SS4 1YH, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	SABAL HEALTH AND PHARMA LTD, LAUNCHPAD, AIRPORT BUSINESS PARK, CHERRY ORCHARD WAY, ROCHFORD, SS4 1YH, 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	11/09/2024

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

SABAL HEALTH AND PHARMA LTD, LAUNCHPAD, AIRPORT BUSINESS PARK, CHERRY ORCHARD WAY, ROCHFORD, SS4 1YH, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance

DEXTROMETHORPHAN
HYDROBROMIDE (2000007835)

3rd Country Manufacturer

DIVI'S LABORATORIES LIMITED, UNIT 1, LINGOJIGUDEM VILLAGE,
CHOUTUPPAL MANDAL, YADADRI BHUVANAGIRI DISTRICT,
TELANGANA, IN-508252, INDIA

3rd Country Distributor

IBUPROFEN LYSINE
(2000011938)

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

PHENYLEPHRINE
HYDROCHLORIDE (2000008067)

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

IBUPROFEN (1000008918)

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

CAFFEINE (1000007507)

SHANDONG XINHUA PHARMACEUTICAL CO LIMITED, EAST CHEMICAL
ZONE OF ZIBO HIGH & NEW TECHNOLOGY DEVELOPMENT ZONE,
ZHANGDIAN DISTRICT, ZIBO, SHANDONG, CN-255 075, CHINA

2. IMPORTATION AND DISTRIBUTION OPERATIONS

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Distribution

DEXTROMETHORPHAN HYDROBROMIDE (2000007835)

IBUPROFEN LYSINE (2000011938)

PHENYLEPHRINE HYDROCHLORIDE (2000008067)

IBUPROFEN (1000008918)

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