

# 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 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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