

# 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, SPA HOUSE, 69 SOUTHEND ROAD, HOCKLEY, SS5 4PZ, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	SABAL HEALTH AND PHARMA LIMITED, SPA HOUSE, 69 SOUTHEND ROAD, HOCKLEY, SS5 4PZ, 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	16/04/2024

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 LIMITED**, SPA HOUSE, 69 SOUTHEND ROAD, HOCKLEY, SS5 4PZ, UNITED KINGDOM

### 2. IMPORTATION AND DISTRIBUTION OPERATIONS

#### A Importation

##### Active Substance

##### 3rd Country Manufacturer

##### 3rd Country Distributor

TAMOXIFEN CITRATE  
(2000007386)

**EXCELLA GMBH & CO KG**, NUERNBERGER STRASSE 12, FEUCHT, D-90537, GERMANY

BACLOFEN (1000009324)

**EXCELLA GMBH & CO KG**, NUERNBERGER STRASSE 12, FEUCHT, D-90537, GERMANY

DEXTROMETHORPHAN  
(1000003241)

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

PHENYLEPHRINE  
(1000009891)

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

GRISEOFULVIN (1000001953)

**CHIFENG PHARMACEUTICAL COMPANY LIMITED**, 84 YIDONG  
STREET, CHIFENG, HONGSHAN DISTRICT, INNER MONGOLIA, CN-024  
001, CHINA

METHOTREXATE DISODIUM  
(4000003566)

**EXCELLA GMBH & CO KG**, NUERNBERGER STRASSE 12, FEUCHT, D-  
90537, GERMANY

CAFFEINE (1000007507)

**SHANDONG XINHUA PHARMACEUTICAL CO LIMITED**, 14 DONGYI  
ROAD, ZHANGDIAN DISTRICT, ZIBO, SHANDONG, CN-255005, CHINA

CODEINE PHOSPHATE  
(2000007940)

**PALLA PHARMA NORWAY AS**, GRUVEVEIEN 1, KRAGERO, NO-3770,  
NORWAY

DILTIAZEM HYDROCHLORIDE  
(2000007763)

**LUSOCHIMICA S.P.A.**, VIA GIOTTO 9, LOMAGNA LC, I-23871, ITALY

TERBUTALINE SULPHATE  
(2000007383)

**LUSOCHIMICA S.P.A.**, VIA GIOTTO 9, LOMAGNA LC, I-23871, ITALY

TRAMADOL (1000007320)

**CHEMAGIS LIMITED**, 3 HASHLOSHA STREET, TEL AVIV, IL-61090,  
ISRAEL

IBUPROFEN LYSINE  
(2000011938)

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

SALBUTAMOL (1000009712)

**LUSOCHIMICA S.P.A.**, VIA GIOTTO 9, LOMAGNA LC, I-23871, ITALY

IBUPROFEN (1000008918)

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

## 2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution  
TAMOXIFEN CITRATE (2000007386)  
BACLOFEN (1000009324)  
DEXTROMETHORPHAN (1000003241)  
PHENYLEPHRINE (1000009891)

GRISEOFULVIN (1000001953)  
METHOTREXATE DISODIUM (4000003566)  
CAFFEINE (1000007507)  
CODEINE PHOSPHATE (2000007940)  
DILTIAZEM HYDROCHLORIDE (2000007763)  
TERBUTALINE SULPHATE (2000007383)  
TRAMADOL (1000007320)  
IBUPROFEN LYSINE (2000011938)  
SALBUTAMOL (1000009712)  
IBUPROFEN (1000008918)

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