

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

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