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 20075

2. Name or corporate name of registrant ACCORD HEALTHCARE LIMITED

3. Permanent or legal address of registrant

ACCORD HEALTHCARE LIMITED, GROUND FLOOR, SAGE HOUSE, 319

PINNER ROAD, HARROW, HA1 4HF, UNITED KINGDOM

4. Address(es) of site(s) where registered activities take

place

ACCORD HEALTHCARE LIMITED, EDGEFIELD AVENUE, NEWCASTLE

UPON TYNE, NE3 3NB, 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 18/10/2024

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

ACCORD HEALTHCARE LIMITED, EDGEFIELD AVENUE, NEWCASTLE UPON TYNE, NE3 3NB, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

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A Importation

Active Substance 3rd Country Manufacturer 3rd Country Distributor

TRAMADOL HYDROCHLORIDE (2000008034)

API Registration Number: UK API 20075

WANBURY LIMITED, 10TH FLOOR, B-WING, BSEL TECH PARK, SECTOR 30A, OPPOSITE VASHI RAILWAY STATION, VASHI, NAVI MUMBAI, MAHARASHTRA, IN-400 703, INDIA

Issue Date: 18 Oct 2024

FARMSON PHARMACEUTICAL GUJARAT PVT.

LIMITED., PLOT NO. 14 GIDC INDUSTRIAL ESTATE, NANDESARI, VADODARA DISTRICT, GUJARAT, IN-

391340, INDIA

ATABAY KIMYA SANAYI VE TICARET AS.

ACIBADEM, KOFTUNCU SOKAK NO. 1, KADIKOY,

ISTANBUL, TR-81010, TURKEY

ATABAY KIMYA SANAYI VE TICARET AS,

ACIBADEM, KOFTUNCU SOKAK NO. 1, KADIKOY, ISTANBUL, TR-81010, TURKEY

FARMSON PHARMACEUTICAL GUJARAT

PVT. LIMITED., PLOT NO. 14 GIDC INDUSTRIAL ESTATE, NANDESARI,

VADODARA DISTRICT, GUJARAT, IN-391340,

INDIA

ALCALIBER SA, AVENIDA DEL RIO VENTALOMAR CODEINE

PARACETAMOL

(1000009609)

(2000007813)

API Registration Number: UK API 20075

PHOSPHATE 1, POLIGONO MARIA DE BENQUERENCIA,

(2000007940) TOLEDO, E-45007, SPAIN

CAFFEINE SIEGFRIED PHARMACHEMIKALIEN MINDEN GMBH

(1000007507)KARLSTRASSE 15, MINDEN, D-32423, GERMANY

SARACA LABORATORIES LIMITED, PLOT NO. 320, RANITIDINE

EAST AVENUE, 1ST FLOOR, SWAMY AYYAPPA **HYDROCHLORIDE**

HOUSING SOCIETY LTD, MADHAPUR,

HYDERABAD, TELANGANA, IN 500081, INDIA

ALENDRONIC ACID IPCA, P.O. SEJAVATA, RATLAM, MADHYA

(1000002993) PRADESH, IN-457002, INDIA

Issue Date: 18 Oct 2024