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

Registration Number
 Name or corporate name of registrant
 Permanent or legal address of registrant
 Address(es) of site(s) where registered activities take place
 National legal basis of registration
 Registration Number
 UK API 8778
 SIGMA PHARMACEUTICALS PLC, FIFTH FLOOR, WATSON HOUSE, 54-60
 BAKER STREET, LONDON, W1U 7BU, UNITED KINGDOM
 SIGMA PHARMACEUTICALS PLC, UNITS 1 & 3, SIGMA HOUSE 1 & 2, HD HOUSE AND A PLANT, COLONIAL WAY, WATFORD, WD24 4YR, UNITED KINGDOM
 National legal basis of registration
 Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916)
 Name of responsible officer of the competent

Confidential

7. Date 15/04/2025

authority of the member state validating the

registration

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

SIGMA PHARMACEUTICALS PLC, UNITS 1 & 3, SIGMA HOUSE 1 & 2, HD HOUSE AND A PLANT, COLONIAL WAY, WATFORD, WD24 4YR, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

ALLOPURINOL (1000003843)

AMILORIDE HYDROCHLORIDE (2000008529)

AMOXICILLIN TRIHYDRATE (4000006303)

API Registration Number: UK API 8778 Page 1 of 1 Issue Date: 15 Apr 2025