

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 45312 |
| 2. Name or corporate name of registrant | INTERCEPT PHARMA EUROPE LIMITED |
| 3. Permanent or legal address of registrant | INTERCEPT PHARMA EUROPE LIMITED, 1 GLASS WHARF,
BRISTOL, BS2 0ZX, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | INTERCEPT PHARMA EUROPE LIMITED, 1 GLASS WHARF,
BRISTOL, BS2 0ZX, 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 | 31/05/2024 |

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

INTERCEPT PHARMA EUROPE LIMITED, 1 GLASS WHARF, BRISTOL, BS2 0ZX, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance

3rd Country Manufacturer

3rd Country
Distributor

CORDEN PHARMA COLORADO INCORPORATED, 2075 NORTH 55TH
STREET, BOULDER, 80301, UNITED STATES

OBETICHOLIC ACID
(1000018845)

PHARMAZELL SCHWEIZ GMBH, ORISTALSTRASSE 65, LIESTAL, CH-
4410, SWITZERLAND

PHARMACIA & UPJOHN COMPANY LLC, 7000 PORTAGE ROAD,
KALAMAZOO, 49001, UNITED STATES