

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 36456
2. Name or corporate name of registrant	CATALENT NOTTINGHAM LIMITED
3. Permanent or legal address of registrant	CATALENT NOTTINGHAM LIMITED, 8 ORCHARD PLACE, NOTTINGHAM BUSINESS PARK, NOTTINGHAM, NG8 6PX, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	CATALENT NOTTINGHAM LIMITED, 8 ORCHARD PLACE, NOTTINGHAM BUSINESS PARK, NOTTINGHAM, NG8 6PX, 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	09/04/2025

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

CATALENT NOTTINGHAM LIMITED, 8 ORCHARD PLACE, NOTTINGHAM BUSINESS PARK, NOTTINGHAM, NG8 6PX, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance

AVAPRITINIB
(3000019925)

3rd Country Manufacturer

DOTTIKON EXCLUSIVE SYNTHESIS AG, HEMBRUNNSTRASSE 17,
DOTTIKON, CH-5605, SWITZERLAND

EUROFINS CDMO ALPHORA INC., 2884 PORTLAND DRIVE, OAKVILLE ON,
L6H 5W8, CANADA

3rd Country Distributor