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 45886
2. Name or corporate name of registrant	CYCLE PHARMACEUTICALS LIMITED
3. Permanent or legal address of registrant	CYCLE PHARMACEUTICALS LIMITED, BROERS BUILDING, 21 J J THOMSON AVENUE, CAMBRIDGE, CB3 0FA, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	CYCLE PHARMACEUTICALS LIMITED, BROERS BUILDING, 21 J J THOMSON AVENUE, CAMBRIDGE, CB3 0FA, 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	05/06/2026

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

CYCLE PHARMACEUTICALS LIMITED, BROERS BUILDING, 21 J J THOMSON AVENUE, CAMBRIDGE, CB3 0FA, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
NITISINONE (1000000933)	**PHARMARON MANUFACTURING SERVICES (US) LLC**, 498 WASHINGTON STREET, COVENTRY, 02816, UNITED STATES	

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

BETAINE (1000007477)

MHRA-GMDP

NILOTINIB (1000011378)

FINGOLIMOD HYDROCHLORIDE (2000016027)

NITISINONE (1000000933)

MHRA-GMDP

MHRA-GMDP