

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 10866
2. Name or corporate name of registrant	NICOBRAND LIMITED
3. Permanent or legal address of registrant	NICOBRAND LIMITED, UNIT 1, 189 CASTLEROE ROAD, COLERAINE, BT51 3RP, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place	NICOBRAND LIMITED, UNIT 1, 189 CASTLEROE ROAD, COLERAINE, BT51 3RP, 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	29/04/2024

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

NICOBRAND LIMITED, UNIT 1, 189 CASTLEROE ROAD, COLERAINE, BT51 3RP, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

NICOTINE POLACRILEX
2000006474

A	Manufacture of Active Substance by Chemical Synthesis
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Fixing Nicotine to an ion exchange resin
E	General Finishing Steps

	E.1 Physical Processing Steps ion exchange resin bonding, drying and milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

NICOTINE

100009685

B	Extraction of Active Substance from Natural Sources
	B.1 Plant Source Extraction
	B.6 Purification of Extracted Substance - PLANT
E	General Finishing Steps
	E.1 Physical Processing Steps Distillation
	E.2 Primary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing