

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 116
2. Name or corporate name of registrant BAXTER HEALTHCARE LIMITED
3. Permanent or legal address of registrant BAXTER HEALTHCARE LIMITED, CAXTON WAY, THETFORD, IP24 3SE,
UNITED KINGDOM
4. Address(es) of site(s) where registered activities
take place BAXTER HEALTHCARE LIMITED, 2 WAVERTREE BOULEVARD,
WAVERTREE TECHNOLOGY PARK, LIVERPOOL, L7 9PE, UNITED
KINGDOM
BAXTER HEALTHCARE LIMITED, RUTHERFORD CLOSE, WAVERTREE
TECHNOLOGY PARK, LIVERPOOL, L13 1EN, 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 23/04/2024

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

BAXTER HEALTHCARE LIMITED, 2 WAVERTREE BOULEVARD, WAVERTREE TECHNOLOGY PARK, LIVERPOOL, L7 9PE,
UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

ICODEXTRIN
1000007338

A	Manufacture of Active Substance by Chemical Synthesis
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	A.1 Manufacture of Active Substance Intermediates
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Activated carbon treatment
	A.4 Other Icodextrin isolation
E	General Finishing Steps
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution
ICODEXTRIN (1000007338)

Name and address of the site

BAXTER HEALTHCARE LIMITED, RUTHERFORD CLOSE, WAVERTREE TECHNOLOGY PARK, LIVERPOOL, L13 1EN, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

ICODEXTRIN
1000007338

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Activated carbon treatment to remove impurities
	A.4 Other Icodextrin isolation by spray drying
E	General Finishing Steps
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution
 ICODextrin (1000007338)