

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 21540
2. Name or corporate name of registrant ONYX SCIENTIFIC LIMITED
3. Permanent or legal address of registrant ONYX SCIENTIFIC LIMITED, WAYFARER ROAD, SUNDERLAND, SR5 3XA,
UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place ONYX SCIENTIFIC LIMITED, WAYFARER ROAD, SUNDERLAND, SR5 3XA,
UNITED KINGDOM
5. National legal basis of registration ONYX SCIENTIFIC LIMITED, UNITS 95, 96, 97, 98, BUSINESS & INNOVATION
CENTRE, WEARFIELD, SUNDERLAND ENTERPRISE PARK, SUNDERLAND, SR5
2TQ, UNITED KINGDOM
6. Name of responsible officer of the competent authority of the member state validating the registration Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916)
7. Date Confidential
- 12/05/2026

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

ONYX SCIENTIFIC LIMITED, WAYFARER ROAD, SUNDERLAND, SR5 3XA, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

DEUCRICTIBANT MONOHYDRATE
4000016921

A	Manufacture of Active Substance by Chemical Synthesis
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	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) recrystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Filtration/Drying
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

ACTIVE SUBSTANCES FOR CLINICAL TRIALS

1000018046

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Salt Formation and recrystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Filtration/Drying/Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

3-2-(DIMETHYLAMINO)ETHYL - 1H- INDOL-4-YL DIHYDROGEN PHOSPHATE

3000024975

A	Manufacture of Active Substance by Chemical Synthesis
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	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) recrystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Filtration/Drying
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

DL-3,4-METHYLENEDIOXYMETHAMPHETAMINE HYDROCHLORIDE

4000015441

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Salt formation/ recrystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Oven drying, milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution
 DEUCRICTIBANT MONOHYDRATE (4000016921)
 ACTIVE SUBSTANCES FOR CLINICAL TRIALS (1000018046)
 3-2-(DIMETHYLAMINO)ETHYL - 1H- INDOL-4-YL DIHYDROGEN PHOSPHATE (3000024975)
 DL-3,4-METHYLENEDIOXYMETHAMPHETAMINE HYDROCHLORIDE (4000015441)

Name and address of the site

1. MANUFACTURING OPERATIONS

Active substance

ACTIVE SUBSTANCES FOR CLINICAL TRIALS

1000018046

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Salt Formation/recrystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Filtration/Drying/Milling
	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

ACTIVE SUBSTANCES FOR CLINICAL TRIALS (1000018046)