

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
ONYX SCIENTIFIC LIMITED, UNITS 95, 96, 97, 98, BUSINESS & INNOVATION CENTRE, WEARFIELD, SUNDERLAND ENTERPRISE PARK, SUNDERLAND, SR5 2TQ, 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 26/06/2024

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

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

1. MANUFACTURING OPERATIONS

Active substance

DL-3,4-METHYLENEDIOXYMETHAMPHETAMINE HYDROCHLORIDE
4000015441

| | |
|---|---|
| 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) 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

DL-3,4-METHYLENEDIOXYMETHAMPHETAMINE HYDROCHLORIDE (4000015441)

Name and address of the site

ONYX SCIENTIFIC LIMITED, UNITS 95, 96, 97, 98, BUSINESS & INNOVATION CENTRE, WEARFIELD, SUNDERLAND ENTERPRISE PARK, SUNDERLAND, SR5 2TQ, UNITED KINGDOM

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 and purification steps |
| 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 |

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution

ACTIVE SUBSTANCES FOR CLINICAL TRIALS (100018046)

MHRA-GMDP

MHRA

MHRA-GMDP

MHRA