

# 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 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 18/09/2023

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
	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)