

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 40699 |
| 2. Name or corporate name of registrant | APTUIT (OXFORD) LIMITED |
| 3. Permanent or legal address of registrant | APTUIT (OXFORD) LIMITED, 110-111, 115 E-H, 117 AND 150 INNOVATION DRIVE, MILTON PARK, MILTON, ABINGDON, OX14 4RZ, UNITED KINGDOM

APTUIT (OXFORD) LIMITED, 150 BROOK DRIVE, MILTON PARK, ABINGDON, OX14 4SD, UNITED KINGDOM |
| 4. Address(es) of site(s) where registered activities take place | APTUIT (OXFORD) LIMITED, 115E-115H INNOVATION DRIVE, MILTON PARK, MILTON, ABINGDON, OX14 4SA, UNITED KINGDOM

APTUIT (OXFORD) LIMITED, 110-111, 115 E-H, 117 AND 150 INNOVATION DRIVE, MILTON PARK, MILTON, ABINGDON, OX14 4RZ, 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 | 03/06/2024 |

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

APTUIT (OXFORD) LIMITED, 150 BROOK DRIVE, MILTON PARK, ABINGDON, OX14 4SD, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

FROVATRIPTAN SUCCINATE
2000006383

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 crystallisation then drying
E	General Finishing Steps
	E.2 Primary Packaging
	E.3 Secondary Packaging

Active substance

FENFLURAMINE

1000002302

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) Chloride salt formation followed by purification by crystallisation.
E	General Finishing Steps
	E.1 Physical Processing Steps Drying
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

PLERIXAFOR

1000015396

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) FINAL STEP INVOLVES CRYSTALLISATION
E	General Finishing Steps

	E.1 Physical Processing Steps MANUFACTURE INVOLVES DRYING
	E.2 Primary Packaging
	E.3 Secondary Packaging

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution
FENFLURAMINE (1000002302)

Name and address of the site

APTUIT (OXFORD) LIMITED, 115E-115H INNOVATION DRIVE, MILTON PARK, MILTON, ABINGDON, OX14 4SA, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

MAVORIXAFOR
1000021934

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 release followed by crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps 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

FROVATRIPTAN SUCCINATE
2000006383

F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

FENFLURAMINE
100002302

F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

PLERIXAFOR
1000015396

F	Quality Control Testing
	F.1 Physical / Chemical testing

Name and address of the site

APTUIT (OXFORD) LIMITED, 110-111, 115 E-H, 117 AND 150 INNOVATION DRIVE, MILTON PARK, MILTON, ABINGDON, OX14 4RZ, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

MAVORIXAFOR
1000021934

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 release followed by crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps 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

LENALIDOMIDE
1000010236

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) FINAL STEP INVOLVES CRYSTALLISATION
E	General Finishing Steps
	E.1 Physical Processing Steps MANUFACTURE INVOLVES DRYING, MICRONISATION
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

PLERIXAFOR
1000015396

F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

FENFLURAMINE
1000002302

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) Chloride salt formation followed by purification by crystallisation.
E	General Finishing Steps
	E.1 Physical Processing Steps Drying
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

FROVATRIPTAN SUCCINATE

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 crystallisation then drying
E	General Finishing Steps
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

2. IMPORTATION AND DISTRIBUTION OPERATIONS

- B Distribution
- LENALIDOMIDE (1000010236)
 - PLERIXAFOR (1000015396)
 - FENFLURAMINE (1000002302)
 - FROVATRIPTAN SUCCINATE (200006383)