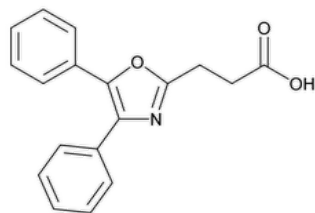


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Oxaprozin

Change to read:



$C_{18}H_{15}NO_3$ 293.32

2-Oxazolepropanoic acid, 4,5-diphenyl-;

4,5-Diphenyl-2-oxazolepropionic acid CAS RN®: 21256-18-8; ▲UNII: MHJ80W9LRB.▲ (USP 1-May-2022)

DEFINITION

Oxaprozin contains NLT 98.0% and NMT 102.0% of oxaprozin ($C_{18}H_{15}NO_3$), calculated on the dried basis.

[NOTE—Because of light sensitivity, protect all oxaprozin samples and *Standard solutions* from light.]

IDENTIFICATION

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197K or 197A
- **B.** The retention time of the oxaprozin peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

Solution A: 0.1% [phosphoric acid](#), pH 2.0 ± 0.1

Mobile phase: [Acetonitrile](#) and *Solution A* (45:55)

Standard solution: 0.2 mg/mL of [USP Oxaprozin RS](#) in [acetonitrile](#)

Sample solution: 0.2 mg/mL of Oxaprozin in [acetonitrile](#)

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 285 nm

Column: 4.6-mm × 15-cm; 5-μm packing [L7](#)

Column temperature: 25°

Flow rate: 1.0 mL/min

Injection volume: 20 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of oxaprozin ($C_{18}H_{15}NO_3$) in the portion of Oxaprozin taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of oxaprozin from the *Sample solution*

r_s = peak response of oxaprozin from the *Standard solution*

C_s = concentration of [USP Oxaprozin RS](#) in the *Standard solution* (mg/mL)

C_u = concentration of Oxaprozin in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.3%

Delete the following:

- ▲ [ARSENIC \(211\), Procedures, Method II](#): NMT 1 ppm ▲ (USP 1-May-2022)

• ORGANIC IMPURITIES

Solution A: 0.1% [phosphoric acid](#), pH 2.0 ± 0.1

Solution B: [Acetonitrile](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	70	30
20	70	30
21	70	30
60	0	100
61	70	30
70	70	30

Diluent A: [Acetonitrile](#), [methylene chloride](#), and [water](#) (48:1:1)

Diluent B: [Acetonitrile](#) and [water](#) (1:1)

Standard stock solution: 200 µg/mL of [USP Oxaprozin RS](#) in [acetonitrile](#)

Standard solution: 5 µg/mL of [USP Oxaprozin RS](#) in *Diluent A* from the *Standard stock solution*

Sensitivity solution: 0.3 µg/mL of [USP Oxaprozin RS](#) in *Diluent A* from the *Standard solution*

System suitability stock solution: 200 µg/mL of [benzil](#) in [acetonitrile](#)

System suitability solution: 10 µg/mL each of [benzil](#) and [USP Oxaprozin RS](#) in *Diluent A* from the *System suitability stock solution* and *Standard stock solution*, respectively

Sample solution A: 1 mg/mL of Oxaprozin prepared as follows. Transfer about 100 mg of Oxaprozin to a 100-mL volumetric flask. Add 2 mL of [methylene chloride](#), 2 mL of [water](#), and 75 mL of [acetonitrile](#). Sonicate after each solvent is added. Dilute with [acetonitrile](#) to volume.

[NOTE—This is used to monitor all known and unknown impurities, except oxaprozin imidazole analog and oxaprozin amide.]

Sample solution B: 1 mg/mL of Oxaprozin in *Diluent B*. [NOTE—This is used to monitor only oxaprozin imidazole analog and oxaprozin amide.]

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 238 nm

Column: 4.6-mm × 15-cm; 5-µm packing [L7](#)

Flow rate: 1.0 mL/min

Injection volume: 20 µL

System suitability

Samples: *Standard solution*, *Sensitivity solution*, and *System suitability solution*

Suitability requirements

Resolution: NLT 3.0 between oxaprozin and benzil, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*