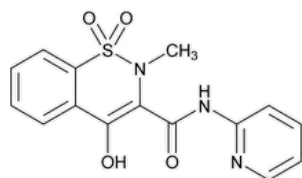


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Piroxicam



$C_{15}H_{13}N_3O_4S$ 331.35

2*H*-1,2-Benzothiazine-3-carboxamide, 4-hydroxy-2-methyl-*N*-2-pyridinyl-, 1,1-dioxide;

4-Hydroxy-2-methyl-*N*-2-pyridyl-2*H*-1,2-benzothiazine-3-carboxamide 1,1-dioxide CAS RN®: 36322-90-4; UNII: 13T406VMAM.

DEFINITION

Piroxicam contains NLT 97.0% and NMT 103.0% of piroxicam ($C_{15}H_{13}N_3O_4S$).

IDENTIFICATION

• **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197M](#). Do not dry specimens.

Delete the following:

▲ • **B.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Ultraviolet-Visible Spectroscopy: 197U](#)

Solution: 10 µg/mL

Medium: Hydrochloric acid in methanol (1 in 1200)

Acceptance criteria: Meets the requirements ▲ (USP 1-Dec-2020)

Delete the following:

▲ • **C.** [THIN-LAYER CHROMATOGRAPHY \(201\)](#)

Diluent: Chloroform and methanol (1:1)

Standard solution: 1 mg/mL of [USP Piroxicam RS](#) in Diluent

Sample solution: 1 mg/mL in Diluent

Chromatographic system

(See [Chromatography \(621\)](#), [Thin-Layer Chromatography](#).)

Absorbent: 0.25-mm layer of chromatographic silica gel

Application volume: 20 µL

Developing solvent system: Toluene and glacial acetic acid (95:5)

Analysis

Samples: Standard solution and Sample solution

Allow the spots to dry, and develop the chromatogram in the *Developing solvent system* until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, and air-dry. Place the plate in the developing chamber, and develop as before. Remove the plate from the chamber, mark the solvent front, and air-dry. Locate the spots on the plate by viewing under short-wavelength UV light.

Acceptance criteria: The R_F value of the principal spot of the *Sample solution* corresponds to that of the *Standard solution*. ▲ (USP 1-Dec-2020)

Add the following:

▲ • **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. ▲ (USP 1-Dec-2020)

ASSAY

Change to read:

• PROCEDURE

▲ **Solution A:** Mix 1 mL of [phosphoric acid](#) with 1000 mL of [water](#).

Solution B: [Acetonitrile](#)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0.0	65	35
2.0	65	35
6.0	5	95
6.1	65	35
11.0	65	35

Diluent: [Methanol](#)

Standard solution: 0.05 mg/mL of [USP Piroxicam RS](#) in *Diluent*. Sonicate to dissolve, if needed.

Sample solution: 0.05 mg/mL of Piroxicam in *Diluent*. Sonicate to dissolve, if needed.

Chromatographic system

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

Mode: LC

Detector: UV 340 nm

Column: 4.6-mm × 15-cm; 3.5-μm packing [L1](#)

Temperatures

Autosampler: 4°

Column: 35°

Flow rate: 1 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%▲ (USP 1-Dec-2020)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of piroxicam ($C_{15}H_{13}N_3O_4S$) in the portion of Piroxicam taken:

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

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

r_S = peak response of piroxicam from the *Standard solution*

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

C_U = concentration of Piroxicam in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–103.0%

IMPURITIES

Add the following:

▲• **LIMIT OF PIROXICAM RELATED COMPOUND B**

Solution A, Solution B, Mobile phase, Diluent, and Chromatographic system: Proceed as directed in the Assay.

