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Piroxicam Compounded Oral Suspension

DEFINITION

Piroxicam Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of piroxicam ($C_{15}H_{13}N_3O_4S$).

Prepare Piroxicam Compounded Oral Suspension 10 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩.

Piroxicam powder	1 g
Ora-Blend,[a] a sufficient quantity to make	100 mL

[a] Perrigo, Minneapolis, MN.

Pour the weighed *Piroxicam powder* into a suitable mortar. Wet the powder with a small amount of *Ora-Blend*, and triturate to make a smooth paste. Add the *Ora-Blend* in small portions almost to volume, and mix thoroughly after each addition. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated container. Add sufficient *Ora-Blend* to bring the preparation to final volume. Shake to mix well.

ASSAY

• **Procedure**

Mobile phase: Mix 500 mL of methanol and 500 mL of 0.1 M sodium acetate, and adjust with phosphoric acid to a pH of 4.0. Add 10 mL of acetonitrile, filter, and degas.

Standard solution: 0.2 mg/mL of piroxicam prepared from USP Piroxicam RS in methanol

Sample solution: Shake thoroughly each bottle of Oral Suspension. Transfer 1.0 mL of the Oral Suspension into a 50-mL volumetric flask, dilute with methanol to volume, and mix well to dissolve. Pass through a PVDF filter of 0.45-µm pore size, discarding the first 3 mL of filtrate.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 361 nm

Column: 3.9-mm × 15-cm; 4-µm packing L7

Flow rate: 1.0 mL/min

Injection volume: 5 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for piroxicam is about 4.0 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of piroxicam ($C_{15}H_{13}N_3O_4S$) in the portion of Oral Suspension 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 piroxicam in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.7–4.7

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store at 2°–8° or at controlled room temperature.

• **Labeling:** Label it to indicate that it is to be well-shaken before use, and to state the *Beyond-Use Date*.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored at 2°–8° or controlled room temperature

• **USP Reference Standards** ⟨11⟩

USP Piroxicam RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
PIROXICAM COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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