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Piroxicam Compounded Cream

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

Prepare Piroxicam Compounded Cream as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Piroxicam	3 g
White Petrolatum	25 g
Stearyl Alcohol	15 g
Propylparaben	0.06 g
Methylparaben	0.15 g
Propylene Glycol	12.0 g
Sodium Lauryl Sulfate	1 g
Sodium Hydroxide, 1 N	2.5 mL
Purified Water, a sufficient quantity to make	100 g

In an appropriate container (final weight tared), mix the *White Petrolatum* and *Stearyl Alcohol* together, and heat to 80 ± 5° to form a clear oil phase. In a separate container, mix the *Propylparaben*, *Methylparaben*, *Propylene Glycol*, *Sodium Lauryl Sulfate*, and about 30 mL of *Purified Water* together, and heat to 80 ± 5° to form a clear aqueous phase. Add the aqueous phase to the oil phase with continuous stirring, and allow it to cool to 50° to form an emulsion. In a mortar, triturate the *Piroxicam* with the *Sodium Hydroxide* to form a suspension. Using additional *Purified Water* to rinse the mortar, add the piroxicam suspension to the previously prepared emulsion, transferring the suspension stepwise and quantitatively to the emulsion. Add sufficient *Purified Water* with stirring to bring to final weight. Package, and label.

ASSAY

• **Procedure**

Solution A: 2.7 g/L of citric acid and 5.4 g/L of dibasic sodium phosphate in *Purified Water*. Pass through a filter of 0.45-µm pore size.

Mobile phase: Methanol and *Solution A* (50:50). Filter, and degas.

Diluent: 0.01 N methanolic hydrochloric acid prepared by diluting 0.9 mL of hydrochloric acid with methanol to a final volume of 1 L

Standard solution: Dissolve an accurately weighed quantity of USP Piroxicam RS in 2 mL of chloroform, and dilute with *Diluent* to obtain a solution with a nominal concentration of about 50 µg/mL of piroxicam.

Sample solution: Add 340 mg of Cream to 4 mL of chloroform and 150 mL of *Diluent*. Shake the mixture on a wrist action shaker for 15 min, and dilute with *Diluent* to 200 mL. Pass the solution through a filter of 0.45-µm pore size, and discard the first 5 mL of the filtrate.

Blank: Add 340 mg of *Purified Water* to 4 mL of chloroform and 150 mL of *Diluent*. Shake the mixture on a wrist action shaker for 15 min, and dilute with *Diluent* to 200 mL. Pass the solution through a filter of 0.45-µm pore size, and discard the first 5 mL of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Columns

Guard: 4.6-mm × 2-cm; packing L1

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Analytical: 4.6-mm × 30-cm; 10-µm packing L1

Flow rate: 1.0 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for piroxicam is about 7 min.]

Suitability requirements

Relative standard deviation: NMT 2.8% for replicate injections

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

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

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Piroxicam RS in the *Standard solution* (µg/mL)

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

Acceptance criteria: 90.0%–110.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in a tight, light-resistant, plastic resealable container. Store at controlled room temperature.
- **BEYOND-USE DATE:** NMT 90 days after the date on which it was compounded when stored at controlled room temperature
- **LABELING:** Label it to state the *Beyond-Use Date.*
- **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 CREAM	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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