Status: Currently Official on 16-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-8571FEED-22A1-4645-82E7-B3C2083E50B2_1_en-US
DOI: https://doi.org/10.31003/USPNF_M68330_01_01
DOI Ref: uuw8f

Pramoxine Hydrochloride Cream

DEFINITION

Pramoxine Hydrochloride Cream contains NLT 90.0% and NMT 110.0% of the labeled amount of pramoxine hydrochloride ($C_{17}H_{27}NO_3 \cdot HCl$) in a suitable water-miscible base.

IDENTIFICATION

- **A.**

Standard: 50 mg of USP Pramoxine Hydrochloride RS

Sample: Nominally 50 mg of pramoxine hydrochloride from a quantity of Cream

Analysis: Dissolve the *Standard* and the *Sample* separately in a mixture of 25 mL of methanol and 75 mL of ether, and extract each with three 25-mL portions of a mixture of equal volumes of 3 N hydrochloric acid and water. Discard the methanol–ether solutions, render the combined extracts alkaline with 25 mL of 5 N sodium hydroxide, and extract the pramoxine with 50 mL of chloroform. Evaporate the clear chloroform extracts with the aid of a current of air to dryness.

Acceptance criteria: The UV absorption spectrum of a solution (1 in 100,000) of the residue so obtained from the *Sample*, in 0.1 N hydrochloric acid, exhibits maxima and minima at the same wavelengths as that of a similar solution of the residue similarly obtained from the *Standard*.

- **B.**

Sample: A 5-mg portion of the pramoxine obtained in *Identification* test *A*

Analysis: To the *Sample* add 1 drop of nitric acid. To the yellow solution cautiously add 5 drops of ammonium hydroxide.

Acceptance criteria: A red-brown precipitate is formed.

ASSAY

- **Procedure**

Buffer: Dissolve 3.5 g of dibasic potassium phosphate in 100 mL of water. Adjust the solution by the addition of phosphoric acid solution (1:1) to a pH of 7.5 ± 0.1.

Mobile phase: Acetonitrile, *Buffer*, and water (22:1:17)

Internal standard solution: 4 µL/mL of dibutyl phthalate in methanol

Standard stock solution: 2 mg/mL of USP Pramoxine Hydrochloride RS in methanol

Standard solution: Transfer 10 mL of the *Standard stock solution* and 5 mL of the *Internal standard solution* into a 100-mL volumetric flask, and dilute with methanol to volume.

Sample solution: Transfer nominally 18 mg of pramoxine hydrochloride from a portion of Cream to a glass-stoppered, 250-mL conical flask. Add 15.0 mL of isopropyl alcohol and 40.0 mL of methanol, and heat on a steam bath, with swirling, to dissolve the Cream. Add 40.0 mL of methanol and 5.0 mL of the *Internal standard solution*. Cool the flask to a temperature of 10° or less to precipitate the waxes, and filter the solution.

Chromatographic system

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

Mode: LC

Detector: UV 224 nm

Columns

Guard: 4.6-mm × 3-cm; packing L1

Analytical: 4-mm × 30-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for pramoxine hydrochloride and dibutyl phthalate are about 0.8 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.4 between pramoxine hydrochloride and dibutyl phthalate

Relative standard deviation: NMT 2.0% in three replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of pramoxine hydrochloride ($C_{17}H_{27}NO_3 \cdot HCl$) in the portion of Cream taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of pramoxine hydrochloride to the internal standard from the *Sample solution*

R_S = peak response ratio of pramoxine hydrochloride to the internal standard from the *Standard solution*

C_S = concentration of USP Pramoxine Hydrochloride RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Minimum Fill ⟨755⟩:** Meets the requirements

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** It meets the requirements of the tests for the absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **USP Reference Standards ⟨11⟩**

USP Pramoxine Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
PRAMOXINE HYDROCHLORIDE CREAM	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-8571FEED-22A1-4645-82E7-B3C2083E50B2_1_en-US

DOI: https://doi.org/10.31003/USPNF_M68330_01_01

DOI ref: uuw8f