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Pramoxine Hydrochloride Jelly

DEFINITION

Pramoxine Hydrochloride Jelly contains NLT 94.0% and NMT 106.0% of the labeled amount of pramoxine hydrochloride ($C_{17}H_{27}NO_3 \cdot HCl$).

IDENTIFICATION

• **A.**

Sample solution: Place nominally 5 mg of pramoxine hydrochloride from a quantity of Jelly in a glass-stoppered conical flask. Add 25 mL of chloroform, and shake for 15 min. Filter into a small porcelain evaporating dish, and evaporate in a current of air on a steam bath.

Analysis: Add 1 drop of nitric acid to the residue. To the resulting yellow solution cautiously add 5 drops of ammonium hydroxide.

Acceptance criteria: A red-brown precipitate is formed.

ASSAY

• **Procedure**

Standard solution: 150 µg/mL of USP Pramoxine Hydrochloride RS in 0.5 N sulfuric acid

Sample solution

[Note—If emulsions form, 2–5 mL of alcohol may be added to separate the phases.]

Transfer nominally 15 mg of pramoxine hydrochloride from a quantity of Jelly to a small beaker, and dissolve the Jelly in 0.1 N sulfuric acid, using four 5-mL portions. Warm each portion on a steam bath, and transfer to a 125-mL separator. Shake the separator vigorously after each transfer to complete the dissolution of the Jelly. To the cooled solution in the separator add 20 mL of ether, shake carefully, and proceed as directed in *Salts of Organic Nitrogenous Bases* ⟨501⟩, *Assay Preparation*, beginning with "filter the acid phase into a second 125-mL separator", except to combine the final 0.5 N sulfuric acid extracts in a 100-mL volumetric flask. Dilute with the acid to volume.

Instrumental conditions

Mode: UV

Analytical wavelength: 286 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Proceed as directed in *Salts of Organic Nitrogenous Bases* ⟨501⟩, *Procedure*, diluting 20.0 mL each of the *Standard solution* and the *Sample solution* with 0.5 N sulfuric acid to 50.0 mL.

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

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

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

Acceptance criteria: 94.0%–106.0%

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, preferably in collapsible tubes.

• **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 JELLY	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

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