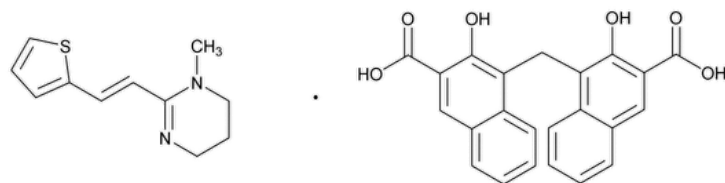


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Pyrantel Pamoate



$C_{11}H_{14}N_2S \cdot C_{23}H_{16}O_6$ 594.68

Pyrimidine, 1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl) ethenyl]-, (E)-, compd. with 4,4'-methylenebis[3-hydroxy-2-naphthalenecarboxylic acid] (1:1);

(E)-1,4,5,6-Tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine 4,4'-methylenebis[3-hydroxy-2-naphthoate] (1:1) CAS RN®: 22204-24-6; UNII: 81BK194Z5M.

DEFINITION

Pyrantel Pamoate contains NLT 97.0% and NMT 103.0% of pyrantel pamoate ($C_{34}H_{30}N_2O_6S$), calculated on the dried basis.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K or 197A
- **B.** The retention time of the major peaks due to pyrantel base and pamoic acid of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

[NOTE—Use low-actinic glassware in preparing solutions of pyrantel pamoate, or otherwise protect the solutions from unnecessary exposure to bright light. Complete the Assay without prolonged interruption.]

Mobile phase: Acetonitrile, glacial acetic acid, diethylamine, and water (92.8: 3: 1.2: 3)

[NOTE—Increasing the amount of acetonitrile in the *Mobile phase* increases retention times. Increasing the amount of acetic acid, water, and diethylamine decreases retention times. Should the *Mobile phase* need to be adjusted, maintain the ratios among acetic acid, diethylamine, and water (1: 0.4: 1).]

Standard solution: 80 µg/mL of [USP Pyrantel Pamoate RS](#) in *Mobile phase*

Sample solution: 80 µg/mL of Pyrantel Pamoate in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 288 nm

Column: 4.6-mm × 25-cm; 5-µm packing [L3](#)

Flow rate: 1 mL/min

Injection volume: 20 µL

Run time: NLT 2.5 times the retention times of pyrantel

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for pamoic acid and pyrantel are 0.6 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 10.0 between pyrantel and pamoic acid

Tailing factor: NMT 1.3 for the pyrantel peak

Relative standard deviation: NMT 1.0% for the pyrantel peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of pyrantel pamoate ($C_{34}H_{30}N_2O_6S$) in the portion of Pyrantel Pamoate taken:

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

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

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

C_S = concentration of [USP Pyrantel Pamoate RS](#) in the *Standard solution* (µg/mL)

C_U = concentration of Pyrantel Pamoate in the *Sample solution* (µg/mL)

Acceptance criteria: 97.0%–103.0% on the dried basis

OTHER COMPONENTS

• CONTENT OF PAMOIC ACID

Mobile phase: Acetonitrile, glacial acetic acid, diethylamine, and water (92.8: 3: 1.2: 3)

[NOTE—Increasing the amount of acetonitrile in the *Mobile phase* increases retention times. Increasing the amount of acetic acid, water, and diethylamine decreases retention times. Should the *Mobile phase* need to be adjusted, maintain the ratios among acetic acid, diethylamine, and water (1: 0.4: 1).]

Standard solution: 52 µg/mL of [USP Pamoic Acid RS](#) in *Mobile phase*

Sample solution: 80 µg/mL of Pyrantel Pamoate in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 288 nm

Column: 4.6-mm × 25-cm; 5-µm packing [L3](#)

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of pamoic acid ($C_{23}H_{16}O_6$) in the portion of Pyrantel Pamoate taken:

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

r_U = peak response of pamoic acid from the *Sample solution*

r_S = peak response of pamoic acid from the *Standard solution*

C_S = concentration of [USP Pamoic Acid RS](#) in the *Standard solution* (µg/mL)

C_U = concentration of Pyrantel Pamoate in the *Sample solution* (µg/mL)

Acceptance criteria: 63.4%–67.3% of pamoic acid, calculated on the dried basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#)

Sample: 1.33 g

Acceptance criteria: NMT 0.5%

Change to read:

• LIMIT OF IRON

(See [▲Iron \(241\)](#), [Procedures, Procedure 1](#) ▲ (CN 1-Jun-2023) .)

Analysis: To the residue obtained in the test for *Residue on Ignition*, add hydrochloric acid and nitric acid (3:2) and evaporate on a steam bath to dryness. Dissolve the residue in 2 mL of hydrochloric acid with the aid of gentle heat. Add 18 mL of hydrochloric acid, dilute with water to