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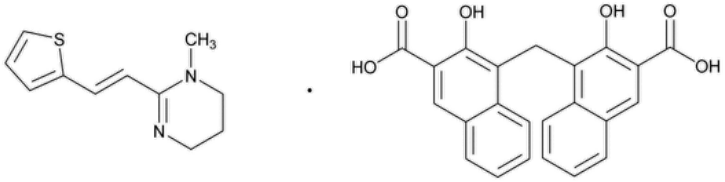
Pyrantel Pamoate



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

50 mL, and mix. Dilute 5 mL of this solution with water to 47 mL.

Acceptance criteria: NMT 0.0075%

- **Organic Impurities**

Diluent: Glacial acetic acid, diethylamine, and water (5:2:5)

Mobile phase: Acetonitrile and *Diluent* (92.8: 7.2). [Note—Prepare the solutions immediately before use, and protect from light at all stages.]

Standard stock solution: 0.8 mg/mL of USP Pyrantel Pamoate RS prepared as follows. Dissolve using 7% of the final volume of *Diluent*, and dilute with acetonitrile to volume.

Standard solution: 4 µg/mL of USP Pyrantel Pamoate RS in *Mobile phase* from the *Standard stock solution*

System suitability stock solution: 0.2 mg/mL of USP Pyrantel Related Compound A RS and 40 µg/mL of USP Pyrantel Pamoate RS prepared as follows. Dissolve a quantity of USP Pyrantel Related Compound A RS first in the *Standard stock solution*, using 5% of the final volume, and dilute with *Diluent* to volume.

System suitability solution: 4 µg/mL of USP Pyrantel Related Compound A RS and 0.8 µg/mL of USP Pyrantel Pamoate RS in *Mobile phase* from the *System suitability stock solution*

Sensitivity solution: 0.2 µg/mL of USP Pyrantel Pamoate RS in *Mobile phase* from the *Standard solution*

Sample solution: 0.8 mg/mL of Pyrantel Pamoate prepared as follows. Dissolve the sample in 7% of the final volume of *Diluent*. Dilute with acetonitrile to volume.

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: 1.0 mL/min

Injection volume: 20 µL

System suitability

Samples: *System suitability solution* and *Sensitivity solution*

Suitability requirements

Resolution: NLT 4.0 between pyrantel and pyrantel related compound A, *System suitability solution*

Tailing factor: NMT 1.5 for the pyrantel peak, *System suitability solution*

Relative standard deviation: NMT 10.0% for the pyrantel peak, *System suitability solution*

Signal-to-noise ratio: NLT 10.0, *Sensitivity solution*

Analysis

Samples: *Standard solution*, *System suitability solution*, and *Sample solution*

[Note—Record the chromatograms for about 4 times the retention time of pyrantel. Disregard any peak in the *Sample solution* having an area less than one-tenth the principal peak in the *Standard solution*.]

Calculate the percentage of pyrantel related compound A 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 related compound A from the *Sample solution*

r_S = peak response of pyrantel related compound A from the *System suitability solution*

C_S = concentration of USP Pyrantel Related Compound A RS in the *System suitability solution* (µg/mL)

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

Calculate the percentage of impurity B or any unspecified impurity in the portion of Pyrantel Pamoate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of impurity B or any unspecified impurity 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)

F = relative response factor (see *Table 1*)

Acceptance criteria: See *Table 1*. The reporting threshold is 0.05%.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Pamoic acid[a]	0.5	—	—
Pyrantel (*E*-isomer)	1.0	—	—
Pyrantel related compound A[b]	1.3	—	0.5
Impurity B[c]	1.8	2.5	0.2
Individual unspecified impurities	—	1.0	0.1
Total unspecified impurities	—	—	0.3
Total impurities	—	—	1.0

[a] For identification purposes only.

[b] 1-Methyl-2-[(*Z*)-2-(thiophen-2-yl)ethenyl]-1,4,5,6-tetrahydropyrimidine.

[c] (*E*)-*N*-[3-(Methylamino)propyl]-3-(thiophen-2-yl)prop-2-enamide.

SPECIFIC TESTS

• **Loss on Drying** ⟨731⟩

Analysis: Dry under vacuum at 60° for 3 h.

Acceptance criteria: NMT 2.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed, light-resistant containers.

• **USP Reference Standards** ⟨11⟩

USP Pamoic Acid RS $C_{23}H_{16}O_6$ 388.38

USP Pyrantel Pamoate RS

USP Pyrantel Related Compound A RS

(*Z*)-1-Methyl-2-[2-(2-thiophenyl)vinyl]-1,4,5,6-tetrahydropyrimidine 4,4′-methylenebis[3-hydroxy-2-naphthoate] (1:1).
$C_{11}H_{14}N_2S \cdot C_{23}H_{16}O_6$ 594.68

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

Topic/Question	Contact	Expert Committee
PYRANTEL PAMOATE	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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