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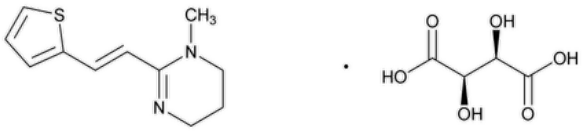
Pyrantel Tartrate



$C_{11}H_{14}N_2S \cdot C_4H_6O_6$ 356.39

Pyrimidine, 1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)ethenyl]-, (*E*)-, (2*R*,3*R*)-2,3-dihydroxybutanedioate (1:1);

(*E*)-1,4,5,6-Tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine tartrate (1:1) CAS RN®: 33401-94-4; UNII: SC82VF0480.

DEFINITION

Pyrantel Tartrate contains NLT 98.0% and NMT 102.0% of pyrantel tartrate ($C_{11}H_{14}N_2S \cdot C_4H_6O_6$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

[Note—Concomitantly prepare potassium bromide dispersions of the Standard and sample. Differences between sets of Standard/sample spectra may occur as a result of differing specimen preparation or environmental conditions.]

• **B.** **Identification Tests—General, *Tartrate* ⟨191⟩**

• **C.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

[Note—Protect all solutions containing Pyrantel Tartrate from light.]

Mobile phase: Acetonitrile, glacial acetic acid, diethylamine, and water (94:2.5:1:2.5)

Standard solution: 0.42 mg/mL of USP Pyrantel Tartrate RS in *Mobile phase*

Sample solution: 0.42 mg/mL of Pyrantel Tartrate in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 316 nm

Column: 4.6-mm × 25-cm; 5-µm packing L3

Flow rate: 1 mL/min

Injection volume: 5 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of pyrantel tartrate ($C_{11}H_{14}N_2S \cdot C_4H_6O_6$) in the portion of Pyrantel Tartrate 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 Pyrantel Tartrate RS in the *Standard solution* (mg/mL)

C_U = concentration of Pyrantel Tartrate in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

• **Organic Impurities**

[Note—Protect all solutions containing Pyrantel Tartrate from light.]

Mobile phase: Acetonitrile, glacial acetic acid, diethylamine, and water (94:2.5:1:2.5)

Standard solution: 0.84 µg/mL of USP Pyrantel Tartrate RS in *Mobile phase*

Sample solution: 0.42 mg/mL of Pyrantel Tartrate in *Mobile phase*

System suitability solution: Expose a portion of the *Sample solution* to short-wavelength UV light for 30 min (Pyrantel Tartrate undergoes partial degradation to *cis*-pyrantel). A degradation level to at least 0.3% of *cis*-pyrantel must be obtained, as shown by the appearance of a corresponding peak in the chromatogram. If it is not obtained, again expose the solution to short-wavelength UV light.

Chromatographic system

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

Mode: LC

Detector: UV 236 and 316 nm

Column: 4.6-mm × 25-cm; 5-µm packing L3

Flow rate: 1 mL/min

Run time: 2.5 times the retention time of pyrantel

Injection volume: 100 µL

System suitability

Sample: *System suitability solution*

[Note—The relative retention times for pyrantel and *cis*-pyrantel are 1.0 and 1.2, respectively.]

Suitability requirements

System suitability requirements must be met at both 236 and 316 nm.

Resolution: NLT 1.5 between pyrantel and *cis*-pyrantel

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity detected at 236 nm in the portion of Pyrantel Tartrate taken:

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

r_U = peak response of each individual impurity detected at 236 nm from the *Sample solution*

r_S = peak response detected at 236 nm from the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

C_U = concentration of the *Sample solution* (mg/mL)

Calculate the percentage of each impurity detected at 316 nm in the portion of Pyrantel Tartrate taken:

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

r_U = peak response of each individual impurity detected at 316 nm from the *Sample solution*

r_S = peak response detected at 316 nm from the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

C_U = concentration of the *Sample solution* (mg/mL)

Acceptance criteria

Any individual impurity: NMT 0.2% of any individual impurity detected at 236 nm; NMT 0.2% of any individual impurity detected at 316 nm

Total impurities: NMT 1.0% of total impurities detected at 236 nm; NMT 1.0% of total impurities detected at 316 nm

SPECIFIC TESTS

• **pH** ⟨791⟩

Sample solution: 10.0 mg/mL in carbon dioxide-free water

Acceptance criteria: 3.3–3.7

• **Loss on Drying** ⟨731⟩

Analysis: Dry at 105° for 4 h.

Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers protected from light, and store at room temperature.

• **Labeling:** Label it to indicate that it is for veterinary use only.

• **USP Reference Standards** ⟨11⟩

USP Pyrantel Tartrate RS

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

Topic/Question	Contact	Expert Committee
PYRANTEL TARTRATE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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