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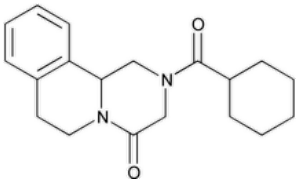
Praziquantel



$C_{19}H_{24}N_2O_2$ 312.41

4*H*-Pyrazino[2,1-*a*]isoquinolin-4-one, 2-(cyclohexylcarbonyl)-1,2,3,6,7,11b-hexahydro-;

2-(Cyclohexylcarbonyl)-1,2,3,6,7,11b-hexahydro-4*H*-pyrazino[2,1-*a*]isoquinolin-4-one CAS RN®: 55268-74-1; UNII: 6490C9U457.

DEFINITION

Praziquantel contains NLT 98.5% and NMT 101.0% of praziquantel ($C_{19}H_{24}N_2O_2$), calculated on the dried basis.

IDENTIFICATION

Change to read:

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

• **B.** 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**

Mobile phase: Acetonitrile and water (60:40)

Standard solution: 0.18 mg/mL of USP Praziquantel RS in *Mobile phase*

Sample solution: 0.18 mg/mL of Praziquantel in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4-mm × 25-cm; 10-µm packing L1

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of praziquantel ($C_{19}H_{24}N_2O_2$) in the portion of Praziquantel 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 Praziquantel RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 98.5%–101.0% on the dried basis

IMPURITIES

- **Residue on Ignition ⟨281⟩:** NMT 0.1%
- **Limit of Phosphate**

Solution A: Dissolve 250 mg of cupric sulfate and 4.5 g of ammonium acetate in sufficient 2 N acetic acid to obtain 100 mL of solution.

Solution B: 30 mg/mL of ammonium molybdate

Solution C: Grind in a mortar 5 g of sodium sulfite, 94.3 g of sodium metabisulfite, and 700 mg of 4-amino-3-hydroxy-1-naphthalenesulfonic acid. Dissolve 1.5 g of this mixture in 10 mL of water, heating gently if necessary. Use this solution only when freshly prepared.

Standard stock solution: 100 µg/mL of phosphate $(PO_4)^{3-}$ prepared as follows. Dissolve 143.3 mg of dried monobasic potassium phosphate in water to make 1000 mL of solution.

Standard solution: 5 µg/mL of phosphate $(PO_4)^{3-}$ from the *Standard stock solution*

Sample solution: 10 mg/mL of Praziquantel, prepared as follows. Add 30 mL of water to 500 mg of sample, and heat to boiling. Allow to cool, and filter, collecting the filtrate in a 50-mL volumetric flask. Wash the filter with water, collect the washings in the volumetric flask, and dilute with water to volume.

Analysis: Treat 10 mL of the *Standard solution* and 10 mL of the *Sample solution* as follows. To each, add 5 mL of *Solution A*, 2 mL of *Solution B*, 1 mL of *Solution C*, and 1 mL of perchloric acid solution (3 in 100); mix; and allow to stand for 15 min.

Acceptance criteria: The *Sample solution* does not have a blue color that is darker than that of the *Standard solution* (0.05%).

- **Organic Impurities**

Mobile phase and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: 0.04 mg/mL each of USP Praziquantel Related Compound A RS, USP Praziquantel Related Compound B RS, and USP Praziquantel Related Compound C RS in *Mobile phase*

Sample solution: 20 mg/mL of Praziquantel in *Mobile phase*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentages of praziquantel related compound A, praziquantel related compound B, or praziquantel related compound C in the portion of Praziquantel taken:

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

r_U = peak response of praziquantel related compound A, praziquantel related compound B, or praziquantel related compound C from the *Sample solution*

r_S = peak response of praziquantel related compound A, praziquantel related compound B, or praziquantel related compound C from the *Standard solution*

C_S = concentration of USP Praziquantel Related Compound A RS, USP Praziquantel Related Compound B RS, or USP Praziquantel Related Compound C RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Praziquantel related compound A[a]	0.8	0.2
Praziquantel	1.0	—
Praziquantel related compound B[b]	1.8	0.2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Praziquantel related compound C[c]	2.1	0.2

[a] 2-Benzoyl-1,2,3,6,7,11b-hexahydro-4*H*-pyrazino [2,1-*a*]isoquinolin-4-one.

[b] 2-(Cyclohexylcarbonyl)-2,3,6,7-tetrahydro-4*H*-pyrazino [2,1-*a*]isoquinolin-4-one.

[c] 2-(*N*-Formylhexahydrohippuroyl-1,2,3,4-tetrahydroisoquinolin-1-one.

SPECIFIC TESTS

• **Loss on Drying ⟨731⟩**

Analysis: Dry a sample in a vacuum at a pressure not exceeding 5 mm of mercury at 50° over phosphorus pentoxide for 2 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards ⟨11⟩**

USP Praziquantel RS

USP Praziquantel Related Compound A RS

2-Benzoyl-1,2,3,6,7,11b-hexahydro-4*H*-pyrazino [2,1-*a*]isoquinolin-4-one.

$C_{19}H_{18}N_2O_2$ 306.37

USP Praziquantel Related Compound B RS

2-(Cyclohexylcarbonyl)-2,3,6,7-tetrahydro-4*H*-pyrazino [2,1-*a*]isoquinolin-4-one.

$C_{19}H_{22}N_2O_2$ 310.40

USP Praziquantel Related Compound C RS

2-(*N*-Formylhexahydrohippuroyl-1,2,3,4-tetrahydroisoquinolin-1-one.

$C_{19}H_{22}N_2O_4$ 342.39

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

Topic/Question	Contact	Expert Committee
PRAZIQUANTEL	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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