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Praziquantel Tablets

DEFINITION

Praziquantel Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of $C_{19}H_{24}N_2O_2$.

IDENTIFICATION

• **Procedure**

Standard solution: 6 mg/mL of USP Praziquantel RS in methanol

Sample solution: Equivalent to 30 mg of Praziquantel from a quantity of powdered Tablets, in a centrifuge tube. Add 5 mL of methanol, agitate for 5 min, and centrifuge. Use the clear supernatant.

Chromatographic system

(See *Chromatography ⟨621⟩, Thin-Layer Chromatography*.)

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 10 µL

Developing solvent system: Ethyl acetate

Analysis

Samples: *Standard solution* and *Sample solution*

Apply separately the *Sample solution* and *Standard solution*, each as 1-cm wide bands, to a chromatographic plate. Proceed as directed in the General Chapter. Develop the chromatogram in an unsaturated chamber, using developing solvent, until the solvent front has moved 8 cm. Remove the plate from the chamber, air-dry, and examine under short-wavelength UV light.

Acceptance criteria: The R_F value of the principal band of the *Sample solution* corresponds to that of the *Standard solution.*

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and water (3:2)

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

Sample stock solution: Weigh and finely powder NLT 20 Tablets. Transfer a portion of the powder, equivalent to 150 mg of praziquantel, to a 100-mL volumetric flask. Add 70 mL of *Mobile phase*, sonicate for 5 min, dilute with *Mobile phase* to volume, mix, and filter.

Sample solution: Transfer 3.0 mL of the filtrate to a 25-mL volumetric flask, and dilute with *Mobile phase* to volume.

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 size: 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 $C_{19}H_{24}N_2O_2$ in the portion of Tablets 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 = nominal concentration of praziquantel in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• **Dissolution** ⟨711⟩

For products for human use

Medium: 0.1 N hydrochloric acid containing 2.0 mg of sodium lauryl sulfate per mL; 900 mL

Apparatus 2: 50 rpm

Time: 60 min

Standard solution: Prepare a solution of USP Praziquantel RS in methanol containing (L/90) mg/mL, where L is the Tablet label claim in mg. Transfer 5.0 mL of this solution to a 50-mL volumetric flask, and dilute with *Medium* to volume.

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size.

Detector: UV 263 nm

Blank: *Medium*

Tolerances: NLT 75% (Q) of the labeled amount of $C_{19}H_{24}N_2O_2$ is dissolved.

For products for veterinary use

Medium: 0.1 N hydrochloric acid containing 2.0 mg of sodium lauryl sulfate per mL; 900 mL

Apparatus 2: 50 rpm, with ▲apex▲ (ERR 1-Nov-2020) vessels

Time: 60 min

Mobile phase: Acetonitrile and water (3:2)

Diluent: Mix 600 mL of acetonitrile with 400 mL of pH 7.4 phosphate buffer.

Standard solution: Prepare a solution containing 0.02 mg of USP Praziquantel RS per mL in methanol. Transfer 10.0 mL to a 100-mL volumetric flask, and dilute with *Diluent* to volume. Transfer 4.0 mL to a 100-mL volumetric flask, add 10 mL of 0.1 N hydrochloric acid, and dilute with *Diluent* to volume.

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm, 10-µm packing L1

Flow rate: 1.5 mL/min

Injection size: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0%

Analysis:

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of praziquantel dissolved in the portion of Tablets taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of $C_{19}H_{24}N_2O_2$ is dissolved

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **USP Reference Standards ⟨11⟩**

USP Praziquantel RS

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

Topic/Question	Contact	Expert Committee
PRAZIQUANTEL TABLETS	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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