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Paroxetine Tablets

DEFINITION

Paroxetine Tablets contain an amount of Paroxetine Hydrochloride equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of paroxetine ($C_{19}H_{20}FNO_3$).

IDENTIFICATION

Change to read:

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**

Sample: Transfer a quantity of finely powdered Tablets, equivalent to 90 mg of paroxetine, to a suitable flask. Add 100 mL of 0.1 N hydrochloric acid, and stir for 1 h. Transfer the mixture to a separatory funnel, and add 1.5 mL of ammonium hydroxide to make the solution alkaline. Add 100 mL of ethyl ether to the funnel, and shake for 2 min. Transfer the organic layer into the necessary number of centrifuge tubes, and centrifuge for 10 min. Recombine the clarified extracts, add 1 drop of water and 0.5 mL of hydrochloric acid, stir, and evaporate to dryness under a stream of nitrogen. Dry the residue in an oven at 90° for 1 h.

Acceptance criteria: Meet the requirements

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

ASSAY

• **Procedure**

Buffer: Water, phosphoric acid, and triethylamine (100:0.6:0.3)

Mobile phase: Acetonitrile and *Buffer* (30:70)

Standard solution: 0.1 mg/mL of USP Paroxetine Hydrochloride RS in methanol

Sample stock solution: 0.5 mg/mL of paroxetine from NLT 20 Tablets in methanol prepared as follows. Transfer an amount of finely powdered Tablets equivalent to NLT 100 mg of paroxetine to a suitable volumetric flask. Dissolve in methanol. Dilute with methanol to volume. Centrifuge a portion of the solution for 6 min. Use the supernatant.

Sample solution: Nominally 0.1 mg/mL of paroxetine in methanol, from the *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 295 nm

Column: 4.6-mm × 3.3-cm; 3-µm packing L7

Flow rate: 2 mL/min

Injection volume: 5 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 750 theoretical plates

Tailing factor: NMT 4

Relative standard deviation: NMT 2.0% for paroxetine

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of paroxetine ($C_{19}H_{20}FNO_3$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

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)

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

M_{r1} = molecular weight of paroxetine, 329.37

M_{r2} = molecular weight of paroxetine hydrochloride, 365.83

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Medium: Simulated gastric fluid without enzyme; 900 mL

Apparatus 2: 60 rpm

Time: 60 min

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

Standard stock solution: 0.63 mg/mL of USP Paroxetine Hydrochloride RS in *Medium* prepared as follows. Transfer a suitable quantity of USP Paroxetine Hydrochloride RS to a suitable volumetric flask. Add 5% of the flask volume of methanol, and dissolve. Dilute with *Medium* to volume.

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

Standard solution: Quantitatively dilute the *Standard stock solution* with *Medium* to a concentration near that of the *Sample solution*.

Chromatographic system

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

Mode: LC

Detector: UV 295 nm

Column: 4.6-mm × 3.3-cm; 3-µm packing L7

Flow rate: 2 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 750 theoretical plates

Tailing factor: NMT 4

Relative standard deviation: NMT 2.0% for paroxetine

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of the labeled amount of paroxetine ($C_{19}H_{20}FNO_3$) dissolved based on the peak responses obtained from the *Sample solution* and the *Standard solution*.

Tolerances: NLT 80% (*Q*) of the labeled amount of paroxetine ($C_{19}H_{20}FNO_3$) is dissolved.

Change to read:

• **Uniformity of Dosage Units** ⟨905⟩: ▲Meet the requirements▲ (CN 1-Aug-2023)

Buffer, Mobile phase, Standard solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Sample solution: Nominally 0.1 mg/mL of paroxetine prepared as follows. Place 1 Tablet in a suitable volumetric flask, and add a volume of a hydrochloric acid solution (7 in 1000), equivalent to about 25% of the flask volume. Allow the Tablet to disintegrate. Dilute with methanol to volume. Centrifuge a portion of the solution.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of paroxetine ($C_{19}H_{20}FNO_3$) in the Tablet taken:

$$\text{Result} = (r_U/r_S) \times C_S \times (M_{r1}/M_{r2}) \times V$$

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)

M_{r1} = molecular weight of paroxetine, 329.37

M_{r2} = molecular weight of paroxetine hydrochloride, 365.83

V = volume of the *Sample solution* (mL)

Acceptance criteria: Meet the requirements

▲▲ (CN 1-Aug-2023)

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers, and store at controlled room temperature.
- **USP Reference Standards** ⟨11⟩
  USP Paroxetine Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
PAROXETINE TABLETS	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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