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Amoxapine Tablets

DEFINITION
Amoxapine Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of amoxapine ($C_{17}H_{16}ClN_3O$).

IDENTIFICATION

Change to read:

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

Sample: Triturate a quantity of finely ground Tablets, equivalent to 50 mg of amoxapine, with 10 mL of chloroform, and filter. Evaporate the filtrate on a steam bath to dryness (about 30 min).

• **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**

Solution A: 1.38 g/L of monobasic sodium phosphate in water

Solution B: 113 g/L of tetramethylammonium chloride in water

Mobile phase: Transfer 20.0 mL of *Solution B*, 4.0 mL of dilute phosphoric acid (1 in 5), and 720 mL of acetonitrile to a 2000-mL volumetric flask. Dilute with *Solution A* to volume.

Standard stock solution: 1 mg/mL of USP Amoxapine RS in acetonitrile. Shake by mechanical means to dissolve, and then dilute with acetonitrile to volume.

Standard solution: 0.1 mg/mL from the *Standard stock solution* diluted with *Mobile phase*

Sample stock solution: Nominally 1 mg/mL of amoxapine from NLT 20 finely powdered Tablets prepared as follows. Transfer a suitable quantity of the powder to a volumetric flask. Add 80% of the flask volume of *Mobile phase*, and shake vigorously by mechanical means for 20 min. Dilute with *Mobile phase* to volume, and filter.

Sample solution: 0.1 mg/mL from the *Sample stock solution* diluted with *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; packing L1

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 1200 theoretical plates

Tailing factor: NMT 1.8

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of amoxapine ($C_{17}H_{16}ClN_3O$) in the portion of Tablets taken:

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

r_U = peak response of amoxapine from the *Sample solution*

r_S = peak response of amoxapine from the *Standard solution*

C_S = concentration of USP Amoxapine RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Medium: Simulated gastric fluid (without enzyme); 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Sample solution: Sample per *Dissolution* ⟨711⟩.

Standard solution: USP Amoxapine RS having a concentration similar to the expected *Sample solution* in *Medium*

Instrumental conditions

Analytical wavelength: 294 nm

Analysis

Samples: *Sample solution* and *Standard solution*

Determine the percentage of the labeled amount of amoxapine ($C_{17}H_{16}ClN_3O$) dissolved from UV absorbances of filtered portions of the *Sample solution*, suitably diluted with *Medium*, if necessary.

Calculate the percentage of the labeled amount of amoxapine ($C_{17}H_{16}ClN_3O$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

V = volume of the *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of amoxapine ($C_{17}H_{16}ClN_3O$) is dissolved.

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

ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards** ⟨11⟩

USP Amoxapine RS

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

Topic/Question	Contact	Expert Committee
AMOXAPINE TABLETS	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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