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Bupropion Hydrochloride Tablets

DEFINITION
Bupropion Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$).

IDENTIFICATION

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

Sample: Crush 1 Tablet using a mortar and pestle. Prepare an approximate 1% (w/w) dispersion of the sample in potassium bromide.

Acceptance criteria: The *Sample* shows strong bands at about 1690, 1560, and 1240 cm^{-1} and a weaker band at about 740 cm^{-1}, similar to the reference preparation.

• **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

Change to read:

• **Procedure**

Buffer: 6.8 g/L of monobasic potassium phosphate and 1.164 g/L of sodium hydroxide in water

Mobile phase: Methanol and *Buffer* (65:35)

Diluent: Methanol and water (65:35)

Standard solution: 0.6 mg/mL of USP Bupropion Hydrochloride RS in *Diluent*

Sample stock solution: Nominally 3.0 mg/mL of bupropion hydrochloride in *Diluent* prepared as follows. Transfer an appropriate number of Tablets to a suitable volumetric flask. Add 50% of the flask volume of *Diluent*, and shake by mechanical means until the Tablets have disintegrated (30–60 min). Sonicate for 5 min, dilute with *Diluent* to volume, and mix. Allow to stand for at least 30 min. Use the supernatant.

Sample solution: Nominally 0.6 mg/mL of bupropion hydrochloride from the *Sample stock solution* in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 224 nm

Column: 4.6-mm × 15-cm; 5-µm base-deactivated packing L1

Flow rate: 1.2 mL/min

Injection volume: 10 µL

▲**Run time:** NLT 1.5 times the retention time of bupropion▲ (USP 1-Aug-2021)

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.5

Relative standard deviation: NMT ▲1.0%▲ (USP 1-Aug-2021)

Analysis

▲**Samples:** *Standard solution* and *Sample solution*▲ (USP 1-Aug-2021)

Calculate the percentage of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) in the portion of Tablets taken:

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

r_U = peak area from the *Sample solution*

r_S = peak area from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• **Dissolution** ⟨711⟩

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Standard solution: USP Bupropion Hydrochloride RS at a known concentration in 0.1 N hydrochloric acid

Sample solution: Pass a portion of the solution under test through a suitable filter, and dilute with 0.1 N hydrochloric acid, if necessary.

Instrumental conditions

Mode: UV

Analytical wavelength: 252 nm

Analysis

Samples: *Standard solution* and *Sample solution*

▲Calculate the percentage of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) dissolved:

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

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

D = dilution factor for the *Sample solution*, if necessary

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)▲ (USP 1-Aug-2021)

Tolerances: NLT 80% (Q) of the labeled amount of bupropion hydrochloride ($C_{13}H_{18}ClNO \cdot HCl$) is dissolved.

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

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in tight containers. ▲Store at controlled room temperature.▲ (USP 1-Aug-2021)

• **USP Reference Standards** ⟨11⟩

USP Bupropion Hydrochloride RS

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

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

Chromatographic Database Information: Chromatographic Database

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