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Propafenone Hydrochloride Tablets

DEFINITION

Propafenone Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of propafenone hydrochloride ($C_{21}H_{27}NO_3 \cdot HCl$).

IDENTIFICATION

Change to read:

• **A.** The Δ_{2S} (USP41) retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

Add the following:

• **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. Δ_{2S} (USP41)

ASSAY

Change to read:

• PROCEDURE

Buffer: 0.1 M monobasic potassium phosphate prepared as follows. Dissolve 13.6 g of [monobasic potassium phosphate](#) in 900 mL of [water](#), adjust with [phosphoric acid](#) to a pH of 3.1, and then dilute with [water](#) to 1 L.

Mobile phase: [Acetonitrile](#) and *Buffer* (32:68)

Standard solution: 0.15 mg/mL of [USP Propafenone Hydrochloride RS](#) in *Mobile phase*

Sample stock solution: Nominally 1.5 mg/mL of propafenone hydrochloride Δ_{2S} (USP41) in *Mobile phase* prepared as follows. Δ Transfer an appropriate quantity of propafenone hydrochloride from NLT 20 powdered Tablets to a suitable volumetric flask, and Δ_{2S} (USP41) add *Mobile phase* to Δ_{2S} (USP41) 90% of the total volume. Sonicate for 10 min. Cool to room temperature, and dilute with *Mobile phase* to volume. Stir for 10 min, pass through a suitable filter of 0.45- μ m pore size, and discard the first 5 mL of the filtrate.

Sample solution: Nominally 0.15 mg/mL of propafenone hydrochloride from *Sample stock solution* in *Mobile phase*. Pass through a suitable filter of 0.45- μ m pore size, and discard the first 5 mL of the filtrate.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 250 nm. Δ For *Identification B*, use a diode array detector in the range of 200–400 nm. Δ_{2S} (USP41)

Column: 4.6-mm $\times$ 15-cm; 5- μ m packing [L7](#)

Column temperature: 45°

Flow rate: 1.2 mL/min

Injection volume: 20 μ L

Run time: NLT 3 times the retention time of the propafenone peak

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of propafenone hydrochloride ($C_{21}H_{27}NO_3 \cdot HCl$) in the portion of Tablets taken.

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

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

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

C_S = concentration of [USP Propafenone Hydrochloride RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Medium: 0.1 N [hydrochloric acid](#); 900 mL

Apparatus 2: 75 rpm

Time: 30 min

Standard solution: 0.17 mg/mL of [USP Propafenone Hydrochloride RS](#) in 0.1 N [hydrochloric acid](#) prepared as follows. To a suitable quantity of [USP Propafenone Hydrochloride RS](#) in a suitable volumetric flask, add 0.1 N [hydrochloric acid](#) to fill 75% of the total volume. Place the flask in a water bath at 37° with stirring until completely dissolved. Remove the flask from the water bath, cool to room temperature, and dilute with 0.1 N [hydrochloric acid](#) to volume.

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-μm pore size, and discard the first 5 mL of the filtrate.

Instrumental conditions

Mode: UV

Analytical wavelength: 250 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of propafenone hydrochloride ($C_{21}H_{27}NO_3 \cdot HCl$) dissolved:

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

A_U = absorbance of propafenone from the *Sample solution*

A_S = absorbance of propafenone from the *Standard solution*

C_S = concentration of [USP Propafenone Hydrochloride RS](#) in the *Standard solution* (mg/mL)

L = label claim for propafenone hydrochloride (mg/Tablet)

V = volume of *Medium*, 900 mL

Tolerances: NLT 80% (Q) of the labeled amount of propafenone hydrochloride ($C_{21}H_{27}NO_3 \cdot HCl$) is dissolved.

Change to read:

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements ▲▲2S (USP41)

IMPURITIES

Change to read:

• ORGANIC IMPURITIES

Solution A: 2.61 g/L of [dipotassium hydrogen phosphate](#) in water. Adjust with [phosphoric acid](#) to a pH of 2.5.

Solution B: [Acetonitrile](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	71	

