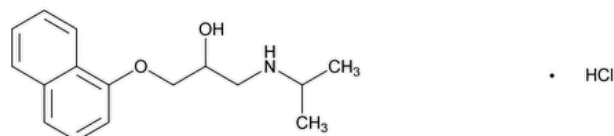


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Propranolol Hydrochloride



$C_{16}H_{21}NO_2 \cdot HCl$ 295.80

2-Propanol, 1-[(1-methylethyl)amino]-3-(1-naphthalenyloxy)-, hydrochloride, (±)-;

(±)-1-(Isopropylamino)-3-(1-naphthyloxy)-2-propanol hydrochloride CAS RN®: 318-98-9; UNII: F8A3652H1V.

DEFINITION

Change to read:

Propranolol Hydrochloride contains NLT 98.0% and NMT $\blacktriangle 102.0\%$ (USP 1-May-2020) of propranolol hydrochloride ($C_{16}H_{21}NO_2 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** $\blacktriangle$ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197M](#) $\blacktriangle$ (CN 1-May-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C.** [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chemical Identification Tests, Chloride](#): Meets the requirements

ASSAY

Change to read:

PROCEDURE

$\blacktriangle$ **Mobile phase:** Mix 1.6 g of [sodium dodecyl sulfate](#) and 0.31 g of [tetrabutylammonium phosphate](#) in a mixture of 1 mL of [sulfuric acid](#), 450 mL of [water](#), and 550 mL of [acetonitrile](#). Adjust with 2 N [sodium hydroxide](#) solution to a pH of 3.3.

Standard solution: 0.2 mg/mL of [USP Propranolol Hydrochloride RS](#) in *Mobile phase*. Sonication may be needed to aid dissolution.

Sample solution: 0.2 mg/mL of Propranolol Hydrochloride in *Mobile phase*. Sonication may be needed to aid dissolution.

Chromatographic system

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

Mode: LC

Detector: UV 292 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)

Flow rate: 1.8 mL/min

Injection volume: 20 μL

Run time: NLT 7 times the retention time of propranolol

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of propranolol hydrochloride ($C_{16}H_{21}NO_2 \cdot HCl$) in the portion of Propranolol Hydrochloride taken.

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

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

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

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

C_U = concentration of Propranolol Hydrochloride in the *Sample solution* (mg/mL)

▲ (USP 1-May-2020)

Acceptance criteria: 98.0%–▲102.0%▲ (USP 1-May-2020) on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

Change to read:

- ▲ **ORGANIC IMPURITIES**

Mobile phase and Chromatographic system: Proceed as directed in the Assay.

System suitability solution: 0.002 mg/mL of [USP Propranolol Related Compound A RS](#) and 2 mg/mL of [USP Propranolol Hydrochloride RS](#) in *Mobile phase*

Standard solution: 0.002 mg/mL of [USP Propranolol Hydrochloride RS](#) in *Mobile phase*

Sensitivity solution: 0.001 mg/mL of [USP Propranolol Hydrochloride RS](#) in *Mobile phase* from *Standard solution*

Sample solution: 2 mg/mL of Propranolol Hydrochloride in *Mobile phase*. Sonication may be needed to aid dissolution.

System suitability

Samples: *System suitability solution*, *Standard solution*, and *Sensitivity solution*

[NOTE—The relative retention times for the impurities are listed in [Table 1](#).]

Suitability requirements

Resolution: NLT 3.0 between propranolol and propranolol related compound A, *System suitability solution*

Relative standard deviation: NMT ▲5.0%,▲ (ERR 1-May-2020) *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each specified and unspecified impurity in the portion of Propranolol Hydrochloride taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of each specified and unspecified impurity from the *Sample solution*

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

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

C_U = concentration of Propranolol Hydrochloride in the *Sample solution* (mg/mL)

F = relative response factor (see [Table 1](#))

Acceptance criteria: See [Table 1](#). The reporting threshold is 0.05%.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Propranolol related compound A	0.6	1.4	0.1
Propranolol	1.0	1.0	



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