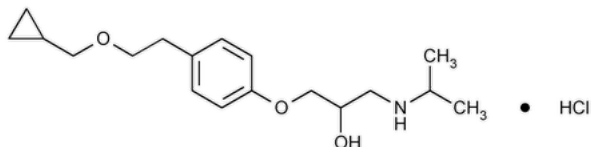


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Betaxolol Hydrochloride



$C_{18}H_{29}NO_3 \cdot HCl$ 343.89

2-Propanol, 1-[4-[2-(cyclopropylmethoxy)ethyl]phenoxy]-3-[(1-methylethyl)amino]-, hydrochloride, ($\pm$);
 ($\pm$)-1-[p-[2-(Cyclopropylmethoxy)ethyl]phenoxy]-3-(isopropylamino)-2-propanol hydrochloride CAS RN®: 63659-19-8; UNII: 6X97D2XT00.

DEFINITION

Betaxolol Hydrochloride contains NLT 98.0% and NMT 102.0% of betaxolol hydrochloride ($C_{18}H_{29}NO_3 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197K
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

Change to read:

- **C.** [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chemical Identification Tests, Chloride](#)

Analysis: Proceed as directed for ▲amine hydrochlorides.▲ (USP 1-May-2021)

Acceptance criteria: Meets the requirements

ASSAY

• PROCEDURE

Buffer: 3.4 g/L of [monobasic potassium phosphate](#) in [water](#), adjusted with [phosphoric acid](#) to a pH of 3.0

Mobile phase: [Acetonitrile](#), [methanol](#), and *Buffer* (175:175:650)

Standard solution: 1 mg/mL of [USP Betaxolol Hydrochloride RS](#) in *Mobile phase*. Sonicate if necessary.

Sample solution: 1 mg/mL of Betaxolol Hydrochloride in *Mobile phase*. Sonicate if necessary.

Chromatographic system

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

Mode: LC

Detector: UV 222 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L7](#)

Flow rate: 1.5 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 3.0

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of betaxolol hydrochloride ($C_{18}H_{29}NO_3 \cdot HCl$) in the portion of Betaxolol Hydrochloride taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• **RESIDUE ON IGNITION (281):** NMT 0.1%

• ORGANIC IMPURITIES

Buffer, Mobile phase, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

System suitability solution: 1 mg/mL of [USP Betaxolol Hydrochloride RS](#) and 30 µg/mL of [USP Betaxolol Related Compound A RS](#) in *Mobile phase*

Standard solution: 0.003 mg/mL of [USP Betaxolol Hydrochloride RS](#) in *Mobile phase*

System suitability

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

[NOTE—The relative retention times for betaxolol related compound A and betaxolol are 0.9 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between the betaxolol related compound A and betaxolol peaks, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Identify the impurities in the *Sample solution* on the basis of the relative retention times in [Table 1](#).

Calculate the percentage of each impurity in the portion of Betaxolol Hydrochloride taken:

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

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

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

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

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

F = relative response factor for each individual impurity (see [Table 1](#))

Acceptance criteria: See [Table 1](#).

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Betaxolol hydroxyethyl analog ^a	0.3	1.3	0.5
Betaxolol related compound A ^b	0.9	1.2	0.5
Betaxolol	1.0	1.0	—
Betaxolol phenol analog ^c	1.6	1.3	0.5
Betaxolol open chain analog ^d	1.7	0.95	0.5
Betaxolol oxirane analog ^e	3.7	1.3	0.5
Any unspecified impurity	—	1.0	0.10
Total impurities	—	—	1.0

^a 1-[4-(2-Hydroxyethyl)phenoxy]-3-(isopropylamino)propan-2-ol.

^b 1-(4-Ethylphenoxy)-3-(isopropylamino)propan-2-ol.

^c 4-[2-(Cyclopropylmethoxy)ethyl]phenol.

^d 1-[4-(2-Butoxyethyl)phenoxy]-3-(isopropylamino)propan-2-ol.

^e 2-([4-(2-Cyclopropylmethoxy)ethyl]phenoxy)methyl)oxirane.