Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2015
Document Type: USP Monographs
DocId: GUID-9899BB8B-37E5-454B-A5A4-B66A3805469D_1_en-US
DOI: https://doi.org/10.31003/USPNF_M9235_01_01
DOI Ref: 5b8gf

Betaxolol Ophthalmic Solution

DEFINITION

Betaxolol Ophthalmic Solution is a sterile, aqueous, isotonic solution of Betaxolol Hydrochloride. It contains a suitable antimicrobial preservative. It contains the equivalent of NLT 90.0% and NMT 110.0% of the labeled amount of betaxolol ($C_{18}H_{29}NO_3$).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

- **Procedure**

Buffer: Dissolve 7.1 g of anhydrous dibasic sodium phosphate in 800 mL of water, adjust with phosphoric acid to a pH of 3.0, and dilute with water to 1000 mL.

Mobile phase: Acetonitrile and *Buffer* (1:1)

Standard solution: 0.11 mg/mL of USP Betaxolol Hydrochloride RS in *Buffer*

Sample solution: Nominally 0.1 mg/mL of betaxolol in *Buffer* from Ophthalmic Solution

Chromatographic system

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

Mode: LC

Detector: UV or diode array 280 nm. [Note—Use the diode array detector to perform *Identification* test *B*.]

Column: 4-mm × 25-cm; packing L1

Flow rate: 1.1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: 0.8–2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of betaxolol ($C_{18}H_{29}NO_3$) in the portion of Ophthalmic Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

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

M_{r1} = molecular weight of betaxolol, 307.43

M_{r2} = molecular weight of betaxolol hydrochloride, 343.89

Acceptance criteria: 90.0%–110.0%

IMPURITIES

- **Organic Impurities**

Mobile phase: Add 5 mL of phosphoric acid to 990 mL of water. Adjust with 2 M ammonium hydroxide to a pH of 3.0, and dilute with water to 1000 mL. Prepare a mixture of this solution and acetonitrile (45:55). Dissolve 3 g of sodium dodecyl sulfate in 450 mL of the mixture.

Standard solution: 2.2 µg/mL of USP Betaxolol Hydrochloride RS in *Mobile phase*

Sample solution: Nominally equivalent to 0.2 mg/mL of betaxolol in *Mobile phase* from Ophthalmic Solution

Chromatographic system

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

Mode: LC

Detector: 220 nm

Column: 4.6-mm × 25-cm; 10-µm packing L1

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 5%

Tailing factor: NMT 2.5

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Ophthalmic Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

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

M_{r1} = molecular weight of betaxolol, 307.43

M_{r2} = molecular weight of betaxolol hydrochloride, 343.89

Acceptance criteria

Single largest individual impurity: NMT 1%

Any other individual impurity: NMT 0.3%

SPECIFIC TESTS

- **Sterility Tests ⟨71⟩:** It meets the requirements when tested as directed for *Test for Sterility of the Product to Be Examined, Membrane Filtration*.
- **pH ⟨791⟩:** 4.0–8.0

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers. Store at room temperature.
- **USP Reference Standards ⟨11⟩**
  USP Betaxolol Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
BETAXOLOL OPHTHALMIC SOLUTION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 40(1)

Current DocID: GUID-9899BB8B-37E5-454B-A5A4-B66A3805469D_1_en-US

DOI: https://doi.org/10.31003/USPNF_M9235_01_01

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