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Bendroflumethiazide Tablets

DEFINITION
Bendroflumethiazide Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of bendroflumethiazide ($C_{15}H_{14}F_3N_3O_4S_2$).

IDENTIFICATION
The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY
• **Procedure**
[Note—Use low-actinic glassware for the *Sample solution* and the *Standard solution*.]

Mobile phase: Dissolve 5.62 g of sodium chloride and 1.97 g of anhydrous sodium sulfate in 1000 mL of water in a 2-L volumetric flask. Add 4.0 mL of glacial acetic acid and 800 mL of methanol, and dilute with water to volume.

Standard solution: 50 µg/mL of USP Bendroflumethiazide RS in methanol

Sample solution: Nominally equivalent to 50 µg/mL from finely powdered Tablets (NLT 20). Initially add methanol (70% of the volume of the flask) and sonicate for 15 min with occasional shaking. Dilute further with methanol to the required concentration, and centrifuge for 15 min.

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

Mode: LC

Detector: UV 270 nm

Column: 4.6-mm × 30-cm; packing L11

Temperature: 35 ± 5°

Flow rate: 1.5 mL/min

Injection size: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 3.0% for five replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_{15}H_{14}F_3N_3O_4S_2$ in the portion of Tablets 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 Bendroflumethiazide RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of bendroflumethiazide in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS
• **Dissolution ⟨711⟩**
[Note—Protect solutions from light throughout this test.]

Medium: 0.01 N hydrochloric acid; 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Detector: UV 271 nm

Sample solution: Sample per *Dissolution ⟨711⟩*.

Standard solution: Prepare a stock solution of USP Bendroflumethiazide RS in an appropriate organic solvent, and dilute this solution with *Medium* to obtain a final concentration similar to the one expected in the *Sample solution*.

Analysis: Determine the amount of $C_{15}H_{14}F_3N_3O_4S_2$ dissolved by using UV absorption on filtered portions of the *Sample solution*, suitably diluted with water, if necessary, in comparison with a *Standard solution* having a known concentration of USP Bendroflumethiazide RS.

Tolerances: NLT 75% (Q) of the labeled amount of $C_{15}H_{14}F_3N_3O_4S_2$ is dissolved.

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

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **USP Reference Standards ⟨11⟩**

USP Bendroflumethiazide RS

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

Topic/Question	Contact	Expert Committee
BENDROFLUMETHIAZIDE TABLETS	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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