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Bumetanide Tablets

DEFINITION

Bumetanide Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of bumetanide ($C_{17}H_{20}N_2O_5S$).

IDENTIFICATION

Change to read:

• **A.** The ▲▲ (USP 1-May-2024) 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:

• **B.** ▲The UV spectrum of the bumetanide peak of the *Sample solution* exhibits maxima and minima at the same wavelengths as those of the corresponding peak of the *Standard solution*, as obtained in the Assay.▲ (USP 1-May-2024)

ASSAY

Change to read:

• **PROCEDURE**

▲**Solution A:** 0.5% (v/v) [formic acid](#) in [water](#) prepared as follows. To a 1-L volumetric flask, add 5 mL of [formic acid](#) and dilute with [water](#) to volume.

Solution B: [Methanol](#)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	60	40
2	60	40
10	20	80
15	20	80
15.1	60	40
20	60	40

Standard stock solution: 0.2 mg/mL of [USP Bumetanide RS](#) in [methanol](#)

Standard solution: 0.1 mg/mL of [USP Bumetanide RS](#) from the *Standard stock solution* in [water](#)

Sample stock solution: Nominally 0.2 mg/mL of bumetanide from Tablets (NLT 10) in a suitable amount of [methanol](#). Initially mix well until the Tablets are disintegrated, centrifuge for about 10 min, and use the supernatant. Sonication may be necessary for complete disintegration.

Sample solution: Nominally 0.1 mg/mL of bumetanide from the *Sample stock solution* in [water](#)

Chromatographic system

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

Mode: LC

Detector: UV 254 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 15-cm; 3.5-µm packing [L1](#)

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution and Sample solution*

Calculate the percentage of the labeled amount of bumetanide ($C_{17}H_{20}N_2O_5S$) in the portion of Tablets taken:

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

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

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

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

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

▲ (USP 1-May-2024)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#).

Test 1

Medium: [Water](#); 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Solution A: 7.505 g/L of [glycine](#) and 5.85 g/L of [sodium chloride](#) in [water](#)

Solution B: *Solution A*, 0.1 N [hydrochloric acid](#), and [water](#) (4:1:45). Adjust, if necessary, with 0.1 N [hydrochloric acid](#) or 0.1 N [sodium hydroxide](#) to a pH of 2.9.

Standard solution: [USP Bumetanide RS](#) at a known concentration in *Medium*

Sample solution: Dilute with *Solution B* as needed.

Instrumental conditions

Mode: Fluorescence

Detectors

Excitation wavelength: 350 nm

Emission wavelength: 450 nm

Analysis

Samples: *Standard solution and Sample solution*

▲ Calculate the percentage of the labeled amount of bumetanide ($C_{17}H_{20}N_2O_5S$) dissolved:

$$\text{Result} = (I_U/I_S) \times [C_S \times V \times (1/L)] \times 100$$

I_U = fluorescence intensity of the *Sample solution*

I_S = fluorescence intensity of the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

▲ (USP 1-May-2024)

Tolerances: NLT 85% (Q) of the labeled amount of bumetanide ($C_{17}H_{20}N_2O_5S$) is dissolved

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium, Apparatus 2, and Time: Proceed as directed in *Test 1*.

Buffer: 2.72 g/L of [potassium phosphate, monobasic](#) in [water](#). Adjust with [1.8 N potassium hydroxide](#) to a pH of 7.0.

Mobile phase: [Acetonitrile](#) and *Buffer* (30:70)

Diluent: [Acetonitrile](#) and [water](#) (50:50)

Standard stock solution: 55.5 µg/mL of [USP Bumetanide RS](#) in *Diluent*

Standard solution: ($L/1000$) µg/mL of [USP Bumetanide RS](#) in *Medium*, from *Standard stock solution*, where L is the label claim in mg/mL

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size