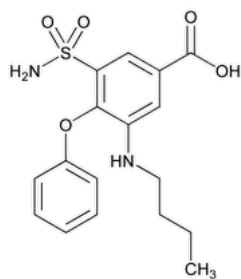


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Bumetanide



$C_{17}H_{20}N_2O_5S$ 364.42
Benzoic acid, 3-(aminosulfonyl)-5-(butylamino)-4-phenoxy-;
3-(Butylamino)-4-phenoxy-5-sulfamoylbenzoic acid CAS RN®: 28395-03-1; UNII: 0Y2S3XUQ5H.

DEFINITION
Bumetanide contains NLT 98.0% and NMT 102.0% of bumetanide ($C_{17}H_{20}N_2O_5S$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197M ▲ or 197A ▲ (USP 1-May-2024)

Change to read:

- **B. ▲**The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*. ▲ (USP 1-May-2024)

Delete the following:

- ▲ • **C. ▲** (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: 0.2 mg/mL of Bumetanide in [methanol](#)

Sample solution: 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

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 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of bumetanide ($C_{17}H_{20}N_2O_5S$) in the portion of Bumetanide 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 = concentration of Bumetanide in the *Sample solution* (mg/mL)

▲ (USP 1-May-2024)

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

IMPURITIES

Change to read:

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%▲ (USP 1-May-2024)

Change to read:

- **ORGANIC IMPURITIES**

▲**Solution A, Solution B, and Mobile phase:** Prepare as directed in the Assay.

Diluent: [Methanol](#) and [water](#) (40:60)

Standard stock solutions: 0.1 mg/mL each of [USP Bumetanide RS](#), [USP Bumetanide Related Compound A RS](#), [USP Bumetanide Related Compound B RS](#), and 0.005 mg/mL of [USP Butyl 3-\(butylamino\)-4-phenoxy-5-sulfamoylbenzoate RS](#) individually prepared as follows.

Transfer suitable amounts each of [USP Bumetanide RS](#), [USP Bumetanide Related Compound A RS](#), [USP Bumetanide Related Compound B RS](#), and [USP Butyl 3-\(butylamino\)-4-phenoxy-5-sulfamoylbenzoate RS](#) to separate suitable volumetric flasks. Add [methanol](#) to about 40% of the total volume of each flask to dissolve the solids. Dilute with [water](#) to volume.

Standard solution: 0.2 μg/mL each of [USP Bumetanide RS](#), [USP Bumetanide Related Compound A RS](#), [USP Bumetanide Related Compound B RS](#), and [USP Butyl 3-\(butylamino\)-4-phenoxy-5-sulfamoylbenzoate RS](#) from the corresponding *Standard stock solutions* in *Diluent*

Sensitivity solution: 0.125 μg/mL each of [USP Bumetanide RS](#), [USP Bumetanide Related Compound A RS](#), [USP Bumetanide Related Compound B RS](#), and [USP Butyl 3-\(butylamino\)-4-phenoxy-5-sulfamoylbenzoate RS](#) from the corresponding *Standard stock solutions* in *Diluent*

Sample solution: 0.2 mg/mL of Bumetanide prepared as follows. To a suitable amount of Bumetanide in a suitable volumetric flask, add [methanol](#) to about 40% of the total volume to dissolve the solids. Dilute with [water](#) to volume.

Chromatographic system: Proceed as directed in the Assay, except for the *Injection volume*.

Injection volume: 50 μL

System suitability

Samples: *Standard solution* and *Sensitivity solution*

Suitability requirements

[NOTE—See [Table 2](#) for the relative retention times.]

Resolution: NLT 20 between bumetanide related compound A and bumetanide related compound B, *Standard solution*

Relative standard deviation: NMT 5.0% for each peak, *Standard solution*

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

Analysis