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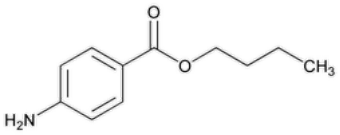
Butamben



$C_{11}H_{15}NO_2$ 193.24

Benzoic acid, 4-amino-, butyl ester;

Butyl *p*-aminobenzoate CAS RN®: 94-25-7; UNII: EFW857872Q.

DEFINITION

Butamben contains NLT 98.0% and NMT 102.0% of butamben ($C_{11}H_{15}NO_2$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197A or 197K▲ (CN 1-May-2020)

• **B.** 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**

Solution A: Add 1.0 mL of 98 percent formic acid to 1 L of water, and mix well.

Solution B: Add 1.0 mL of 98 percent formic acid to 1 L of acetonitrile, and mix well.

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0.0	90	10
1.0	90	10
6.0	50	50
8.5	50	50
8.6	90	10
10.0	90	10

Standard solution: 0.2 mg/mL of USP Butamben RS prepared as follows. Transfer a suitable quantity of USP Butamben RS to an appropriate volumetric flask. Add 10% of the total flask volume of acetonitrile to dissolve, then dilute with water to volume.

Sample solution: 0.2 mg/mL of Butamben prepared as follows. Transfer a suitable quantity of Butamben to an appropriate volumetric flask. Add 10% of the total flask volume of acetonitrile to dissolve, then dilute with water to volume.

Chromatographic system

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

Mode: LC

Detector: UV 285 nm

Column: 2.1-mm × 10-cm; 5-µm packing L1

Flow rate: 0.4 mL/min

Injection volume: 1 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 butamben ($C_{11}H_{15}NO_2$) in the portion of Butamben 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 Butamben RS in the *Standard solution* (mg/mL)

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

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

IMPURITIES

- **Residue on Ignition ⟨281⟩:** NMT 0.2%
- **Organic Impurities**

Solution A, Solution B, Mobile phase, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Diluent: Acetonitrile and water (10:90)

Standard stock solution: 0.1 mg/mL each of USP Butamben RS and USP Aminobenzoic Acid RS prepared as follows. Transfer a suitable quantity of each Reference Standard to an appropriate volumetric flask. Add 10% of the total flask volume of acetonitrile to dissolve, then dilute with water to volume.

Standard solution: 0.2 µg/mL each of USP Butamben RS and USP Aminobenzoic Acid RS from the *Standard stock solution* in *Diluent* [Note—The use of blank injections of *Diluent* may be suitable to reduce carryover between injections of the *Sample solution* and the *Standard solution*, if observed.]

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 10 between the aminobenzoic acid and butamben peaks

Relative standard deviation: NMT 5% for each peak corresponding to aminobenzoic acid and butamben

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of aminobenzoic acid in the portion of Butamben taken:

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

r_U = peak response of aminobenzoic acid from the *Sample solution*

r_S = peak response of aminobenzoic acid from the *Standard solution*

C_S = concentration of USP Aminobenzoic Acid RS in the *Standard solution* (mg/mL)

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

Calculate the percentage of any individual unspecified impurity in the portion of Butamben taken:

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

r_U = peak response of any other individual impurity from the *Sample solution*

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

C_S = concentration of USP Butamben RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: See *Table 2*. Disregard any impurity peak less than 0.05%.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Aminobenzoic acid	0.2	0.10
Butamben	1.0	—
Any unspecified impurity	—	0.10
Total impurities	—	1.0

SPECIFIC TESTS

• **Loss on Drying** ⟨731⟩

Analysis: Dry over phosphorus pentoxide for 3 h.

Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **USP Reference Standards** ⟨11⟩

USP Aminobenzoic Acid RS

Benzoic acid, 4-amino.

$C_7H_7NO_2$ 137.14

USP Butamben RS

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

Topic/Question	Contact	Expert Committee
BUTAMBEN	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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