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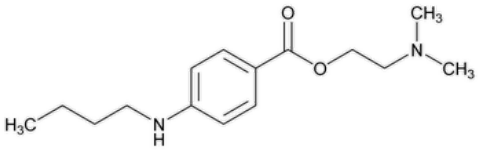
Tetracaine



$C_{15}H_{24}N_2O_2$ 264.36

Benzoic acid, 4-(butylamino)-, 2-(dimethylamino)ethyl ester;

2-(Dimethylamino)ethyl *p*-(butylamino)benzoate CAS RN®: 94-24-6; UNII: 0619F35CGV.

DEFINITION

Tetracaine contains NLT 98.0% and NMT 102.0% of tetracaine ($C_{15}H_{24}N_2O_2$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests** ⟨197⟩, *Infrared Spectroscopy*: **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**

Prepare the standard solutions and sample solutions immediately before use or store them at a temperature of 2°–8°, and protect from light.

Solution A: 1.36 g/L of monobasic potassium phosphate in water is prepared as follows. Dissolve 1.36 g of monobasic potassium phosphate in about 600 mL of water, and add 0.5 mL of phosphoric acid. Dilute with water to 1 L.

Solution B: Acetonitrile

Solution C: 1.0 mL/L of hydrochloric acid

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	80	20
3	80	20
18	40	60
23	40	60
23.1	80	20
28	80	20

Diluent: Acetonitrile and *Solution C* (20:80)

Standard stock solution: 0.46 mg/mL of USP Tetracaine Hydrochloride RS in *Diluent*. Sonicate for 5 min.

Standard solution: 0.046 mg/mL of USP Tetracaine Hydrochloride RS from *Standard stock solution* in *Diluent*

Sample stock solution: 0.4 mg/mL of Tetracaine in *Diluent*. Sonicate for 5 min.

Sample solution: 0.04 mg/mL of Tetracaine from *Sample stock solution* in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 300 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Temperatures

Column: 30°

Autosampler: 4°

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of tetracaine ($C_{15}H_{24}N_2O_2$) in the portion of Tetracaine 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 Tetracaine Hydrochloride RS in the *Standard solution* (mg/mL)

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

M_{r1} = molecular weight of tetracaine, 264.36

M_{r2} = molecular weight of tetracaine hydrochloride, 300.82

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

IMPURITIES

- **Residue on Ignition ⟨281⟩:** NMT 0.1%
- **Organic Impurities**

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

Standard solution: 4.6 µg/mL of USP Tetracaine Hydrochloride RS and 4 µg/mL each of USP Tetracaine Related Compound B RS, USP Tetracaine Related Compound C RS, and USP Aminobenzoic Acid RS in *Diluent*

Sample solution: 1 mg/mL of Tetracaine in *Diluent*

System suitability

Sample: *Standard solution*

[Note—See *Table 2* for the relative retention times.]

Suitability requirements

Resolution: NLT 5.0 between tetracaine and tetracaine related compound B

Relative standard deviation: NMT 5.0% for tetracaine

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of aminobenzoic acid, tetracaine related compound B, and tetracaine related compound C in the portion of Tetracaine taken:

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

r_U = peak response of corresponding tetracaine related compound from the *Sample solution*

r_S = peak response of corresponding tetracaine related compound from the *Standard solution*

C_S = concentration of corresponding tetracaine related compound in the *Standard solution* (mg/mL)

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

Calculate the percentage of each unspecified impurity in the portion of Tetracaine 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 unspecified impurity from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

M_{r1} = molecular weight of tetracaine, 264.36

M_{r2} = molecular weight of tetracaine hydrochloride, 300.82

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

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Aminobenzoic acid[a]	0.3	0.4
Tetracaine hydrochloride	1	—
Tetracaine related compound B	1.7	0.4
Tetracaine related compound C	2.1	0.4
Individual unspecified impurity	—	0.4
Total impurities	—	0.8

[a] 4-Aminobenzoic acid.

SPECIFIC TESTS

• **Loss on Drying ⟨731⟩**

Analysis: Dry under vacuum over phosphorus pentoxide for 18 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **USP Reference Standards ⟨11⟩**

USP Aminobenzoic Acid RS

USP Tetracaine RS

USP Tetracaine Related Compound B RS

4-(Butylamino)benzoic acid.

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

USP Tetracaine Related Compound C RS

Methyl 4-(butylamino)benzoate.

$C_{12}H_{17}NO_2$ 207.35

USP Tetracaine Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
TETRACAINE	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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