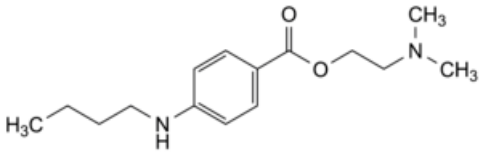
Edition: BP 2025 (Ph. Eur. 11.6 update)

Tetracaine

General Notices

(Ph. Eur. monograph 2909)



$C_{15}H_{24}N_2O_2$ 264.4 *94-24-6*

Action and use

Local anaesthetic.

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DEFINITION

2-(Dimethylamino)ethyl 4-(butylamino)benzoate.

Content

99.0 per cent to 101.0 per cent (dried substance).

CHARACTERS

Appearance

White or almost white, crystalline powder.

Solubility

Very slightly soluble in water, freely soluble in methylene chloride, soluble in ethanol (96 per cent).

mp

About 44 °C.

IDENTIFICATION

Infrared absorption spectrophotometry (2.2.24).

Comparison tetracaine CRS.

TESTS

Appearance of solution

The solution is clear (2.2.1) and colourless (2.2.2, Method II).

Dissolve 2.0 g in ethanol (96 per cent) R and dilute to 10 mL with the same solvent.

Related substances

Liquid chromatography (2.2.29).

Test solution Dissolve 0.100 g of the substance to be examined in acetonitrile R and dilute to 50.0 mL with the same solvent.

Reference solution (a) Dilute 1.0 mL of the test solution to 100.0 mL with acetonitrile R. Dilute 1.0 mL of this solution to 10.0 mL with acetonitrile R.

Reference solution (b) Dissolve 10 mg of 4-aminobenzoic acid R (impurity A), 10 mg of 4-(butylamino)benzoic acid R (impurity B) and 10 mg of methyl 4-(butylamino)benzoate R (impurity C) in acetonitrile R and dilute to 50 mL with the same solvent. Dilute 1 mL of the solution to 10 mL with the test solution.

Column:

— *size*: *l* = 0.15 m, Ø = 4.6 mm;

— *stationary phase*: end-capped octadecylsilyl amorphous organosilica polymer for chromatography R (5 µm);

— *temperature*: 30 °C.

Mobile phase:

— *mobile phase A*: dissolve 1.36 g of potassium dihydrogen phosphate R in water for chromatography R, add 0.5 mL of phosphoric acid R and dilute to 1000 mL with water for chromatography R;

— *mobile phase B*: acetonitrile R;

Time (min)	Mobile phase A (per cent *V/V*)	Mobile phase B (per cent *V/V*)
0 - 3	80	20
3 - 18	80 → 40	20 → 60
18 - 23	40	60

Flow rate 1.5 mL/min.

Detection Spectrophotometer at 300 nm.

Injection 5 µL.

Identification of impurities Use the chromatogram obtained with reference solution (b) to identify the peaks due to impurities A, B and C.

Relative retention With reference to tetracaine (retention time = about 7 min): impurity A = about 0.4; impurity B = about 1.6; impurity C = about 2.2.

System suitability Reference solution (b):

— resolution: minimum 5.0 between the peaks due to tetracaine and impurity B.

Calculation of percentage contents:

— *correction factors*: multiply the peak areas of the following impurities by the corresponding correction factor: impurity B = 0.7; impurity C = 0.7;

— for each impurity, use the concentration of tetracaine in reference solution (a).

Limits:

— *impurities B, C*: for each impurity, maximum 0.15 per cent;

— *impurity A*: maximum 0.05 per cent;

— *unspecified impurities*: for each impurity, maximum 0.10 per cent;

— *total*: maximum 0.3 per cent;

— *reporting threshold*: 0.05 per cent, except for impurity A.

Loss on drying (*2.2.32*)

Maximum 0.5 per cent, determined on 1.000 g by drying *in vacuo* at 30 °C for 2 h.

Sulfated ash (*2.4.14*)

Maximum 0.1 per cent, determined on 1.0 g.

ASSAY

Dissolve 0.300 g in 50 mL of a mixture of 25 volumes of *water R* and 75 volumes of *ethanol (96 per cent) R*. Titrate with *0.1 M hydrochloric acid*, determining the end-point potentiometrically (*2.2.20*).

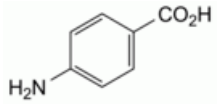
1 mL of *0.1 M hydrochloric acid* is equivalent to 26.44 mg of $C_{15}H_{24}N_2O_2$.

STORAGE

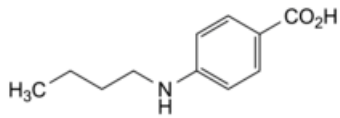
In an airtight container, protected from light.

IMPURITIES

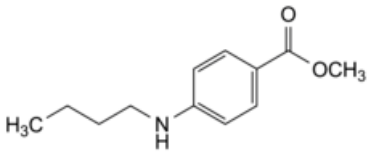
Specified impurities *A, B, C.*



A. 4-aminobenzoic acid,



B. 4-(butylamino)benzoic acid,



C. methyl 4-(butylamino)benzoate.

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