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

Sodium Caprylate

General Notices

Sodium Octanoate

(Ph. Eur. monograph 1471)

$C_8H_{15}NaO_2$ 166.2 *1984-06-1*

Action and use

Excipient.

Ph Eur

DEFINITION

Sodium octanoate.

Content

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

CHARACTERS

Appearance

White or almost white, crystalline powder.

Solubility

Very soluble or freely soluble in water, freely soluble in acetic acid, sparingly soluble in ethanol (96 per cent), practically insoluble in acetone.

IDENTIFICATION

A. Examine the chromatograms obtained in the test for related substances.

Results The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (a).

B. To 0.2 mL of solution S (see Tests) add 0.3 mL of *water R*. The solution gives reaction (b) of sodium (*2.3.1*).

TESTS

Solution S

Dissolve 2.5 g in *carbon dioxide-free water R* and dilute to 25 mL with the same solvent.

Appearance of solution

Solution S is clear (*2.2.1*) and colourless (*2.2.2, Method II*).

pH (*2.2.3*)

8.0 to 10.5 for solution S.

Related substances

Gas chromatography (*2.2.28*): use the normalisation procedure.

Test solution Dissolve 0.116 g in *water R* and dilute to 5 mL with the same solvent. Add 1 mL of a 2.8 per cent *V/V* solution of *sulfuric acid R* and shake with 10 mL of *ethyl acetate R*. Separate the organic layer and dry over *anhydrous sodium sulfate R*.

Reference solution (a) Dissolve 0.10 g of *caprylic acid CRS* in *ethyl acetate R* and dilute to 10 mL with the same solvent.

Reference solution (b) Dilute 1 mL of the test solution to 100 mL with *ethyl acetate R*. Dilute 5 mL of this solution to 50 mL with *ethyl acetate R*.

Column:

— *material*: fused silica;

— *size*: *l* = 30 m, Ø = 0.25 mm;

— *stationary phase*: *macrogol 20 000 2-nitroterephthalate R* (film thickness 0.25 µm).

Carrier gas *helium for chromatography R*.

Flow rate 1.5 mL/min.

Split ratio 1:100.

Temperature:

	Time (min)	Temperature (°C)
Column	0 - 1	100
	1 - 25	100 → 220
	25 - 35	220
Injection port		250
Detector		250

Detection Flame ionisation.

Injection 1 µL.

System suitability Reference solution (b):

— *signal-to-noise ratio*: minimum 5 for the principal peak.

Limits:

— *any impurity*: for each impurity, maximum 0.3 per cent;

— *total*: maximum 0.5 per cent;

— *disregard limit*: 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.05 per cent).

Water (*2.5.12*)

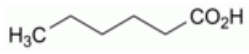
Maximum 3.0 per cent, determined on 1.000 g.

ASSAY

Dissolve 0.150 g in 50 mL of *anhydrous acetic acid R*. Titrate with *0.1 M perchloric acid*, determining the end-point potentiometrically (*2.2.20*).

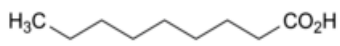
1 mL of *0.1 M perchloric acid* is equivalent to 16.62 mg of $C_8H_{15}NaO_2$.

IMPURITIES

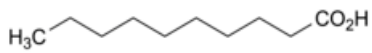


A. hexanoic acid,

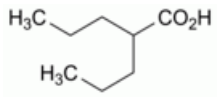
B. heptanoic acid,



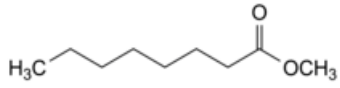
C. nonanoic acid,



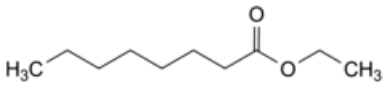
D. decanoic acid,



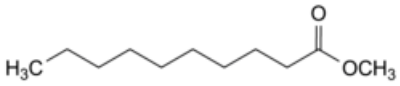
E. 2-propylpentanoic acid (valproic acid),



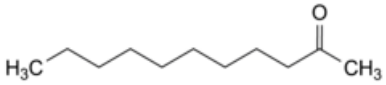
F. methyl octanoate,



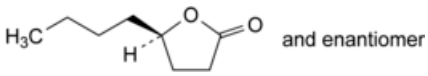
G. ethyl octanoate,



H. methyl decanoate,



I. undecan-2-one,



J. (*RS*)-5-butyltetrahydrofuran-2-one (γ-hydroxyoctanoic acid lactone).

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