



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

Palmitic Acid



[General Notices](#)

(Ph. Eur. monograph 1904)

57-10-3

Action and use

Excipient.

Ph Eur

DEFINITION

Hexadecanoic acid ($C_{16}H_{32}O_2$; M_r 256.4), obtained from fats or oils of vegetable or animal origin.

Content

Minimum 92.0 per cent.

CHARACTERS

Appearance

White or almost white, waxy solid.

Solubility

Practically insoluble in water, soluble in ethanol (96 per cent).

IDENTIFICATION

- A. Freezing point (see Tests).
- B. Acid value ([2.5.1](#)): 216 to 220, determined on 0.1 g.
- C. Examine the chromatograms obtained in the assay.

Results The principal peak in the chromatogram obtained with the test solution is similar in retention time to the principal peak in the chromatogram obtained with the reference solution.

TESTS

Appearance

Heat the substance to be examined to about 75 °C. The resulting liquid is not more intensely coloured than reference solution Y₇ or BY₇ ([2.2.2, Method I](#)).

Acidity

Melt 5.0 g, stir for 2 min in 10 mL of hot [carbon dioxide-free water R](#), cool slowly and filter. To the filtrate add 0.05 mL of [methyl orange solution R](#). No red colour develops.

Freezing point ([2.2.18](#))

60 °C to 66 °C.

Iodine value ([2.5.4](#))

Maximum 1.

Stearic acid

Maximum 6.0 per cent, determined as prescribed in the assay.

ASSAY

Gas chromatography ([2.4.22, Method C](#)) with the following modifications. Prepare the solutions as described in the method but omitting the initial hydrolysis.

Reference solution Prepare the reference solution in the same manner as the test solution using a mixture of 50 mg of [palmitic acid R](#) and 50 mg of [stearic acid R](#) instead of the substance to be examined.

Relative retention With reference to methyl stearate: methyl palmitate = about 0.9.

System suitability:

— [resolution](#): minimum 5.0 between the peaks due to methyl stearate and methyl palmitate.

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