



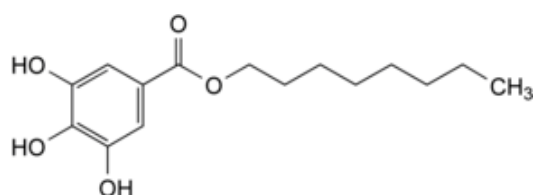
Edition: BP 2025 (Ph. Eur. 11.6 update)

Octyl Gallate



[General Notices](#)

(Ph. Eur. monograph 2057)



$C_{15}H_{22}O_5$ 282.3 1034-01-1

Action and use

Used in treatment of alcohol dependence.

Ph Eur

DEFINITION

Octyl 3,4,5-trihydroxybenzoate.

Content

97.0 per cent to 103.0 per cent (dried substance).

CHARACTERS

Appearance

White or almost white, crystalline powder.

Solubility

Practically insoluble in water, freely soluble in ethanol (96 per cent), practically insoluble in methylene chloride.

IDENTIFICATION

A. Melting point ([2.2.14](#)).

Determine the melting point of the substance to be examined. Mix equal parts of the substance to be examined and [octyl gallate CRS](#) and determine the melting point of the mixture. The difference between the melting points (which are about 101 °C) is not greater than 2 °C.

B. Examine the chromatograms obtained in the test for impurity A.

Results The principal spot in the chromatogram obtained with test solution (b) is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution (a).

TESTS

Impurity A

Thin-layer chromatography ([2.2.27](#)).

Test solution (a) Dissolve 0.20 g of the substance to be examined in [acetone R](#) and dilute to 10 mL with the same solvent.

Test solution (b) Dilute 1.0 mL of test solution (a) to 20 mL with [acetone R](#).

Reference solution (a) Dissolve 10 mg of [octyl gallate CRS](#) in [acetone R](#) and dilute to 10 mL with the same solvent.

Reference solution (b) Dissolve 20 mg of [gallic acid R](#) in [acetone R](#) and dilute to 20 mL with the same solvent.

Reference solution (c) Dilute 1.0 mL of reference solution (b) to 10 mL with [acetone R](#).

Reference solution (d) Dilute 1.0 mL of reference solution (b) to 5 mL with test solution (a).

Plate [TLC silica gel plate R](#).

Mobile phase [anhydrous formic acid R](#), [ethyl formate R](#), [toluene R](#) (10:40:50 V/V/V).

Application 5 µL of test solutions (a) and (b) and reference solutions (a), (c) and (d).

Development Over 2/3 of the plate.

Drying In air for 10 min.

Detection Spray with a mixture of 1 volume of [ferric chloride solution R1](#) and 9 volumes of [ethanol \(96 per cent\) R](#).

System suitability Reference solution (d):

— the chromatogram shows 2 clearly separated principal spots.

Limit Test solution (a):

— *impurity A*: any spot due to impurity A is not more intense than the spot in the chromatogram obtained with reference solution (c) (0.5 per cent).

Chlorides ([2.4.4](#))

Maximum 100 ppm.

To 1.65 g add 50 mL of [water R](#). Shake for 5 min. Filter. 15 mL of the filtrate complies with the test.

[Loss on drying \(2.2.32\)](#)

Maximum 0.5 per cent, determined on 1.000 g by drying in an oven at 70 °C.

[Sulfated ash \(2.4.14\)](#)

Maximum 0.1 per cent, determined on 1.0 g.

ASSAY

Dissolve 0.100 g in [methanol R](#) and dilute to 250.0 mL with the same solvent. Dilute 5.0 mL of the solution to 200.0 mL with [methanol R](#). Measure the absorbance ([2.2.25](#)) at the absorption maximum at 275 nm.

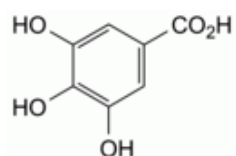
Calculate the content of $C_{15}H_{22}O_5$ taking the specific absorbance to be 387.

STORAGE

In a non-metallic container, protected from light.

IMPURITIES

Specified impurities A.



A. 3,4,5-trihydroxybenzoic acid (gallic acid).

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