

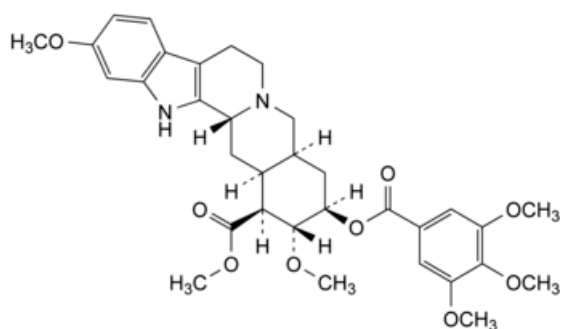


Edition: BP 2025 (Ph. Eur. 11.6 update)

Reserpine

[General Notices](#)

(Ph. Eur. monograph 0528)



$C_{33}H_{40}N_2O_9$ 609 50-55-5

Action and use

Rauwolfia alkaloid; treatment of hypertension.

Ph Eur

DEFINITION

Methyl 11,17 α -dimethoxy-18 β -[(3,4,5-trimethoxybenzoyl)oxy]-3 β ,20 α -yohimban-16 β -carboxylate.

Content

- [reserpine](#): 98.0 per cent to 102.0 per cent (dried substance),
- *total alkaloids*: 99.0 per cent to 101.0 per cent (dried substance).

CHARACTERS

Appearance

White or slightly yellow, small crystals or crystalline powder, darkening slowly on exposure to light.

Solubility

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

IDENTIFICATION

Infrared absorption spectrophotometry ([2.2.24](#)).

Comparison [reserpine CRS](#).

TESTS

[Specific optical rotation](#) ([2.2.7](#))

-116 to -128 (dried substance).

Dissolve 0.250 g in [chloroform R](#) and dilute to 25.0 mL with the same solvent. Examine immediately.

Oxidation products

Dissolve 20 mg in [glacial acetic acid R](#) and dilute to 100.0 mL with the same acid. The absorbance ([2.2.25](#)) measured immediately at the absorption maximum at 388 nm is not greater than 0.10.

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

Maximum 0.5 per cent, determined on 0.500 g by drying *in vacuo* at 60 °C at a pressure not exceeding 0.7 kPa for 3 hours.

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

Maximum 0.1 per cent, determined on 0.5 g.

ASSAY

Total alkaloids

Dissolve 0.500 g in a mixture of 6 mL of [acetic anhydride R](#) and 40 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 60.9 mg of total alkaloids.

[Reserpine](#)

Protect the solutions from light Moisten 25.0 mg with 2 mL of [ethanol \(96 per cent\) R](#), add 2 mL of [0.25 M sulfuric acid](#) and 10 mL of [ethanol \(96 per cent\) R](#), and warm gently to dissolve. Cool and dilute to 100.0 mL with [ethanol \(96 per cent\) R](#). Dilute 5.0 mL of this solution to 50.0 mL with [ethanol \(96 per cent\) R](#). Prepare a reference solution in the same manner using 25.0 mg of [reserpine CRS](#). Place 10.0 mL of each solution separately in 2 boiling-tubes, add 2.0 mL of [0.25 M sulfuric acid](#) and 2.0 mL of a freshly prepared 3 g/L solution of [sodium nitrite R](#). Mix and heat in a water-bath at 55 °C for 35 min. Cool, add 1.0 mL of a freshly prepared 50 g/L solution of [sulfamic acid R](#) and dilute to 25.0 mL with [ethanol \(96 per cent\) R](#). Measure the absorbance ([2.2.25](#)) of each solution at the absorption maximum at 388 nm, using as the compensation liquid 10.0 mL of the same solution prepared at the same time in the same manner, but omitting the sodium nitrite.

Calculate the content of C₃₃H₄₀N₂O₉ from the absorbances measured and the concentrations of the solutions.

STORAGE

Protected from light.

