Noscapine (Noscapinum)

Molecular formula. \( C_{22}H_{23}NO_7 \)

Relative molecular mass. 413.4

Graphic formula.

![Graphic formula of Noscapine](image)

**Chemical name.** Narcotine; (5R)-5-[(1S-6,7-dimethoxyphthalalidyl)-5,6,7,8-tetrahydro-4-methoxy-6-methyl-1,3-dioxolo[4,5-g]isoquinoline; [S-(R*,S*)]-6,7-dimethoxy-3-(5,6,7,8-tetrahydro-4-methoxy-6-methyl-1,3-dioxolo[4,5-g]isoquinolin-5-yl)-1(3H)-isobenzofuranone; CAS Reg. No. 128-62-1.

**Description.** Colourless crystals or a white, crystalline powder; odourless or almost odourless.

**Solubility.** Practically insoluble in water; sparingly soluble in boiling water; slightly soluble in ethanol (~750 g/l) TS and ether R.

**Category.** Antitussive drug.

**Storage.** Noscapine should be kept in a well-closed container.

**Requirements**

**Definition.** Noscapine contains not less than 98.5% and not more than 101.0% of \( C_{22}H_{23}NO_7 \), calculated with reference to the dried substance.

**Identity tests**

- Either test A alone or tests B, C and D may be applied.

  A. Carry out the examination as described under 1.7 Spectrophotometry in the infrared region. The infrared absorption spectrum is concordant with the spectrum obtained from noscapine RS or with the reference spectrum of noscapine.

  B. The absorption spectrum of a 0.050 mg/mL solution in methanol R, when observed between 230 nm and 350 nm, exhibits 2 maxima at about 291 nm and 310 nm and a minimum at about 263 nm. The ratio of the absorbance at 310 nm to that at 291 nm is about 1.2.

  C. To 10 mg add about 0.5 mL of sulfuric acid (~1760 g/l) TS and mix; a greenish yellow solution is formed, which becomes red and finally violet on heating.

  D. Melting temperature, about 175°C.

**Specific optical rotation.** Use a 20 mg/mL solution in hydrochloric acid (0.1 mol/l) VS; \([\alpha]^{20}_{D} = +42° \text{ to } +48°\).

**Sulfated ash.** Not more than 1.0 mg/g.

**Loss on drying.** Dry to constant weight at 105°C; it loses not more than 10 mg/g.

**Related substances.** Carry out the test as described under 1.14.1 Thin-layer chromatography, using silica gel R5 as the coating substance and a mixture of 45 volumes of acetone R, 45 volumes of toluene R, 7 volumes of ethanol (~750 g/l) TS, and 3 volumes of ammonia (~260 g/l) TS as the mobile phase. Apply separately to the plate 10 μl of each of 2 solutions in ethanol (~750 g/l) TS containing (A) 20 mg of the test substance per mL and (B) 0.20 mg of the test substance per mL. After removing the plate from the chromatographic chamber, allow it to dry in air, spray it with iodine (0.1 mol/l) VS, and examine the chromatogram in daylight. Any spot obtained with solution A, other than the principal spot, is not more intense than that obtained with solution B.
**Assay.** Dissolve about 0.5 g, accurately weighed, in 40 mL of glacial acetic acid R1, warming gently, and titrate with perchloric acid (0.1 mol/l) VS as described under 2.6 Non-aqueous titration, Method A. Each mL of perchloric acid (0.1 mol/l) VS is equivalent to 41.34 mg of C<sub>22</sub>H<sub>23</sub>NO<sub>7</sub>. 