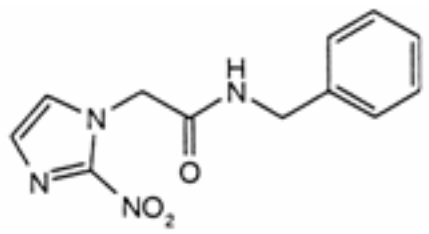
Benznidazole (Benznidazolum)



$C_{12}H_{12}N_4O_3$

Relative molecular mass. 260.3

Chemical name. *N*-Benzyl-2-nitroimidazole-1-acetamide; *N*-benzyl-2-nitro-1-imidazole-acetamide; CAS Reg. No. 22994-85-0.

Description. A yellowish powder; odourless or almost odourless.

Solubility. Practically insoluble in water; sparingly soluble in acetone R; slightly soluble in methanol R; very slightly soluble in ethanol (~750 g/l) TS.

Category. Antiprotozoal drug.

Storage. Benznidazole should be kept in a well-closed container, protected from light.

Requirements

Benznidazole contains not less than **98.5%** and not more than the equivalent of **101.5%** of $C_{12}H_{12}N_4O_3$, calculated with reference to the dried substance.

Identity tests

• Either test A alone or tests B and C 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 benznidazole RS or with the *reference spectrum* of benznidazole.

B. See the test described below under "Related substances". The principal spot obtained with solution A corresponds in position, appearance, and intensity with that obtained with solution B.

C. Melting temperature, about 190 °C.

Sulfated ash. Not more than 1.0 mg/g.

Loss on drying. Dry at 105 °C for 4 hours; it loses not more than 5.0 mg/g.

Related substances. Carry out the test as described under *1.14.1 Chromatography*, Thin-layer chromatography, using silica gel R2 as the coating substance and a mixture of 40 volumes of chloroform R, 40 volumes of ethyl acetate R, 15 volumes of methanol R, and 5 volumes of glacial acetic acid R as the mobile phase. Apply separately to the plate 20 µl of each of 3 solutions in acetone R containing (A) 25 mg of Benznidazole per mL, (B) 25 mg of benznidazole RS per mL, and (C) 125 µg of benznidazole RS per mL. After removing the plate from the chromatographic chamber, allow it to dry in air until the solvents have evaporated, and heat at 110 °C for 10 minutes. Allow it to cool and examine the chromatogram in ultraviolet light (254 nm).

Any spot obtained with solution A, other than the principal spot, is not more intense than that obtained with solution C (0.5%).

Assay. Dissolve about 0.2 g, accurately weighed, in 75 mL of acetic anhydride R, and titrate with perchloric acid (0.1 mol/l) VS as described under 2.6 Non-aqueous titration, Method A, determining the end-point potentiometrically.

Each mL of perchloric acid (0.1 mol/l) VS is equivalent to 26.03mg of $C_{12}H_{12}N_4O_3$.