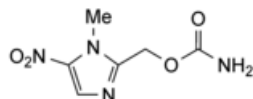




Edition: BP 2025 (Ph. Eur. 11.6 update)

Ronidazole

[General Notices](#)



$\text{C}_6\text{H}_8\text{N}_4\text{O}_4$ 200.2 7681-76-7

Action and use

Antiprotozoal.

DEFINITION

Ronidazole is (1-methyl-5-nitroimidazol-2-yl)methyl carbamate. It contains not less than 98.5% and not more than 101.0% of $\text{C}_6\text{H}_8\text{N}_4\text{O}_4$, calculated with reference to the anhydrous substance.

CHARACTERISTICS

A white to yellowish brown powder; odourless or almost odourless.

Slightly soluble in [water](#), in [chloroform](#) and in [ethanol \(96%\)](#); very slightly soluble in ether.

IDENTIFICATION

- The [infrared absorption spectrum](#), [Appendix II A](#), is concordant with the *reference spectrum* of ronidazole ([RSV 36](#)).
- The [light absorption](#), [Appendix II B](#), in the range 230 to 350 nm of a 0.002% w/v solution in 0.1M [methanolic hydrochloric acid](#) exhibits a maximum only at 270 nm. The [absorbance](#) at the maximum is about 0.64.
- [Melting point](#), about 167°, [Appendix V A](#).

TESTS

[Colour of solution](#)

A 0.5% w/v solution in [methanol](#) is not more intensely coloured than [reference solution Y₆](#), [Appendix IV B](#), Method II.

(1-Methyl-5-nitroimidazol-2-yl)methanol

Carry out the method for [thin-layer chromatography](#), [Appendix III A](#), using [silica gel](#) GF_{254} as the coating substance and a mixture of 5 volumes of [glacial acetic acid](#), 5 volumes of [methanol](#) and 80 volumes of [toluene](#) as the mobile phase. Apply

separately to the plate 20 µL of each of two solutions in [acetone](#) containing (1) 1.0% w/v of the substance being examined and (2) 0.0050% w/v of [\(1-methyl-5-nitroimidazol-2-yl\)methanol BPCRS](#). After removal of the plate, allow it to dry in air and examine under [ultraviolet light \(254 nm\)](#). Any spot in the chromatogram obtained with solution (1) corresponding to (1-methyl-5-nitroimidazol-2-yl)methanol is not more intense than the spot in the chromatogram obtained with solution (2) (0.5%).

[Water](#)

Not more than 0.5% w/w, [Appendix IX C](#). Use 5 g.

[Sulfated ash](#)

Not more than 0.1%, [Appendix IX A](#).

ASSAY

Carry out Method I for [non-aqueous titration](#), [Appendix VIII A](#), using 0.3 g and determining the end point [potentiometrically](#). Each mL of [0.1M perchloric acid VS](#) is equivalent to 20.02 mg $C_6H_8N_4O_4$.

STORAGE

Ronidazole should be protected from light.