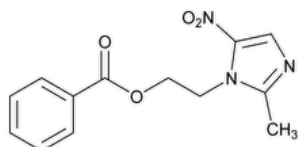


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Metronidazole Benzoate



$C_{13}H_{13}N_3O_4$

275.26

2-(2-Methyl-5-nitroimidazol-1-yl)ethyl benzoate CAS RN®: 13182-89-3; UNII: A355C835XC.

DEFINITION

Metronidazole Benzoate contains NLT 98.5% and NMT 101.0% of metronidazole benzoate ($C_{13}H_{13}N_3O_4$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)
- **B.** The principal spot of the *Sample solution* corresponds to that of *Standard solution A*, as obtained in the test for *Organic Impurities*.

ASSAY

PROCEDURE

Sample solution: Dissolve with stirring 250 mg of Metronidazole Benzoate in 50.0 mL of glacial acetic acid.

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: 0.1 N perchloric acid

Endpoint detection: Potentiometric

Analysis: Titrate the *Sample solution* with *Titrant*. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 27.53 mg of metronidazole benzoate ($C_{13}H_{13}N_3O_4$).

Acceptance criteria: 98.5%–101.0% on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

ORGANIC IMPURITIES

Standard solution A: 0.1 mg/mL of [USP Metronidazole Benzoate RS](#) in acetone

Standard solution B: 0.04 mg/mL of [USP Metronidazole Benzoate RS](#) in acetone from *Standard solution A*

Standard solution C: 0.2 mg/mL each of [USP Metronidazole RS](#) and [USP Tinidazole Related Compound A RS](#) in acetone

Sample solution: 20 mg/mL of Metronidazole Benzoate in acetone

Chromatographic system

(See [Chromatography \(621\)](#), [Thin-Layer Chromatography](#).)

Mode: TLC

Adsorbent: 0.2-mm layer of chromatographic silica gel mixture

Application volume: 10 µL

Developing solvent system: Ethyl acetate

System suitability

Sample: *Standard solution C*

Suitability requirements: The test is valid only if the metronidazole and tinidazole related compound A spots are clearly separated.

Analysis

Samples: *Standard solution A*, *Standard solution B*, *Standard solution C*, and *Sample solution*

Proceed as directed in the chapter. Examine the plate under short-wavelength UV light.

Acceptance criteria: No secondary spot of the *Sample solution* is larger or more intense than the principal spot of *Standard solution A* (0.5%); and NMT three spots, excluding the principal spot, of the *Sample solution* are larger or more intense than the principal spot of *Standard solution B* (0.2%).

SPECIFIC TESTS

• **ACIDITY**

Sample: 2.0 g

Analysis: Neutralize 40 mL of a mixture of dimethylformamide and water (1:1) with hydrochloric acid or 0.02 M sodium hydroxide. Add 0.2 mL of methyl red TS and the *Sample*, mix to dissolve, and titrate with 0.02 M sodium hydroxide.

Acceptance criteria: NMT 0.25 mL is required to produce a color change.

• **LOSS ON DRYING (731).**

Analysis: Dry at 80° for 3 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in well-closed, light-resistant containers. Store at 25°, excursions permitted between 15° and 30°.

• **USP REFERENCE STANDARDS (11).**

[USP Metronidazole RS](#)

[USP Metronidazole Benzoate RS](#)

[USP Tinidazole Related Compound A RS](#)

2-Methyl-5-nitroimidazole.

$C_4H_5N_3O_2$ 127.10

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
METRONIDAZOLE BENZOATE	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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