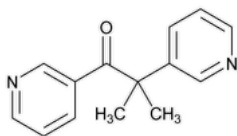


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Metyrapone



$C_{14}H_{14}N_2O$ 226.27

1-Propanone, 2-methyl-1,2-di-3-pyridinyl-;

2-Methyl-1,2-di-3-pyridyl-1-propanone CAS RN[®]: 54-36-4; UNII: ZS9KD92H6V.

DEFINITION

Metyrapone contains NLT 98.0% and NMT 102.0% of metyrapone ($C_{14}H_{14}N_2O$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- A. ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197M](#) ▲ (CN 1-MAY-2020)

Change to read:

- B. ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Ultraviolet-Visible Spectroscopy: 197U](#) ▲ (CN 1-MAY-2020)

Sample solution: 10 µg/mL in 1 N sulfuric acid

Acceptance criteria: Meets the requirements

ASSAY

PROCEDURE

Diluent: 1 N sulfuric acid

Standard solution: 10 µg/mL of [USP Metyrapone RS](#) in Diluent

Sample solution: 10 µg/mL of Metyrapone in Diluent

Instrumental conditions

Mode: UV

Analytical wavelength: 260 nm

Cell: 1 cm

Blank: Diluent

Analysis

Samples: Standard solution and Sample solution

Calculate the percentage of metyrapone ($C_{14}H_{14}N_2O$) in the portion of Metyrapone taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the Sample solution

A_S = absorbance of the Standard solution

C_S = concentration of [USP Metyrapone RS](#) in the Standard solution (µg/mL)

C_U = concentration of Metyrapone in the Sample solution (µg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

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

ORGANIC IMPURITIES

Standard stock solution: 0.2 mg/mL of [USP Metyrapone RS](#) in methanol

Standard solution A: 40 µg/mL of [USP Metyrapone RS](#) in methanol

Standard solution B: 20 µg/mL of [USP Metyrapone RS](#) in methanol

Sample solution: 20 mg/mL of Metyrapone in methanol

Chromatographic system

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

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 5 µL

Developing solvent system: Chloroform and methanol (48:3)

Analysis

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

Apply each of the *Samples* separately to the TLC plate. Position the plate in a chromatographic chamber, and develop the chromatograms in the *Developing solvent system* until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and dry under a stream of nitrogen for about 10 min. Position the dried plate once again in the same chromatographic chamber, and again develop the chromatograms until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and dry under a current of warm air for about 15 min. Examine the plate under short-wavelength UV light, and compare the intensities of any secondary spots observed in the chromatogram of the *Sample solution* with those of the principal spots in the chromatograms of the *Standard solutions*.

Acceptance criteria: The intensity of any secondary spot from the *Sample solution* is NMT the principal spot from *Standard solution A* (0.2%), and the sum of the intensities of the secondary spots from the *Sample solution* corresponds to NMT 1.0%.

SPECIFIC TESTS

- [Loss on Drying \(731\)](#)

Analysis: Dry a sample under vacuum at room temperature for 6 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, protected from heat and light.

- [USP REFERENCE STANDARDS \(11\)](#)

[USP Metyrapone RS](#)

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

Topic/Question	Contact	Expert Committee
METYRAPONE	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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