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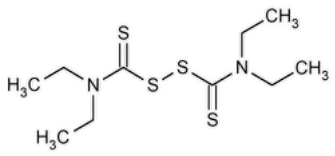
Disulfiram



$C_{10}H_{20}N_2S_4$ 296.54

Thioperoxydicarbonic diamide $[(H_2N)C(S)]_2S_2$, tetraethyl-;

Bis(diethylthiocarbamoyl) disulfide CAS RN®: 97-77-8; UNII: TR3MLJ1UAI.

DEFINITION

Disulfiram contains NLT 98.0% and NMT 102.0% of $C_{10}H_{20}N_2S_4$.

IDENTIFICATION

- **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

- **Procedure**

Buffer: 6.8 g/L of monobasic potassium phosphate in water. Adjust with 45% potassium hydroxide solution to a pH of 7.0.

Mobile phase: Methanol and *Buffer* (7:3)

Standard stock solution: 1 mg/mL of USP Disulfiram RS in alcohol. [Note—Discard this solution after 5 days.]

Standard solution: 0.02 mg/mL of USP Disulfiram RS from the *Standard stock solution* diluted with *Mobile phase*. [Note—Prepare the *Standard solution* fresh daily.]

Sample stock solution: Transfer 50 mg of Disulfiram to a 50-mL volumetric flask, add 40 mL of alcohol, sonicate for 5 min to completely dissolve, cool, and dilute with alcohol to volume. [Note—Discard this solution after 5 days.]

Sample solution: 0.02 mg/mL of Disulfiram from the *Sample stock solution* diluted with *Mobile phase*. [Note—Prepare the *Sample solution* fresh daily.]

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 250 nm

Column: 4-mm × 15-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection size: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 1800 theoretical plates

Tailing factor: NMT 2

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_{10}H_{20}N_2S_4$ in the portion of Disulfiram taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Disulfiram RS in the *Standard solution* (µg/mL)

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

Acceptance criteria: 98.0%–102.0%

IMPURITIES

Inorganic Impurities

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

Change to read:

• ▲**Selenium ⟨291⟩, *Procedures, Procedure 1*** ▲ (CN 1-Jun-2023) **:** 30 ppm

[Note—Perform this test only if selenium is a known inorganic process impurity.]

SPECIFIC TESTS

• **Melting Range or Temperature, *Class I* ⟨741⟩:** 69°–72°

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **USP Reference Standards ⟨11⟩**

USP Disulfiram RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
DISULFIRAM	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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