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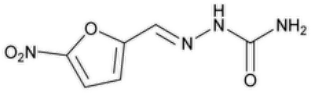
Nitrofurazone



$C_6H_6N_4O_4$ 198.14

Hydrazinecarboxamide, 2-[(5-nitro-2-furanyl)methylene]-;

5-Nitro-2-furaldehyde semicarbazone CAS RN®: 59-87-0; UNII: X8XI70B5Z6.

DEFINITION

Nitrofurazone contains NLT 98.0% and NMT 102.0% of nitrofurazone ($C_6H_6N_4O_4$), calculated on the dried basis.

[NOTE—Avoid at all times exposing solutions of nitrofurazone to direct sunlight, excessive heat, strong fluorescent lighting, and alkaline materials.]

IDENTIFICATION

Change to read:

• **A.** ▲**SPECTROSCOPIC IDENTIFICATION TESTS ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-MAY-2020)

Change to read:

• **B.** ▲**SPECTROSCOPIC IDENTIFICATION TESTS ⟨197⟩, *Ultraviolet-Visible Spectroscopy*: 197U**▲ (CN 1-MAY-2020)

Sample solution: 8 µg/mL, prepared as directed in the *Assay*

Acceptance criteria: The ratio A_{306}/A_{375} is NMT 0.25.

ASSAY

• **PROCEDURE**

Standard stock solution: 0.4 mg/mL of USP Nitrofurazone RS prepared as follows. Transfer 100 mg of USP Nitrofurazone RS to a 250-mL volumetric flask. Dissolve in 50 mL of dimethylformamide, and dilute with water to volume.

Standard solution: 8 µg/mL of USP Nitrofurazone RS in water from *Standard stock solution*

Sample stock solution: 0.4 mg/mL of Nitrofurazone prepared as follows. Transfer 100 mg of Nitrofurazone to a 250-mL volumetric flask. Dissolve in 50 mL of dimethylformamide, and dilute with water to volume.

Sample solution: 8 µg/mL of Nitrofurazone in water from *Sample stock solution*

Instrumental conditions

Mode: UV-Vis

Analytical wavelength: 375 nm

Cell: 1 cm

Blank: Water

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of nitrofurazone ($C_6H_6N_4O_4$) in the portion of Nitrofurazone 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 Nitrofurazone RS in the *Standard solution* (µg/mL)

C_U = concentration of Nitrofurazone 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**

Mobile phase: Acetonitrile and water (40:60)

Peak identification solution: 0.1 mg/mL each of USP Nitrofurazone Related Compound A RS and USP Nitrofurfural Diacetate RS in *Mobile phase*

System suitability solution: 0.1 mg/mL each of USP Nitrofurazone RS and USP Nitrofurantoin RS in *Mobile phase*

Standard solution: 5 µg/mL of USP Nitrofurazone RS in *Mobile phase*

Sample solution: 1 mg/mL of Nitrofurazone in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 310 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

Run time: NLT 10 times the retention time of nitrofurazone

System suitability

Samples: *System suitability solution* and *Standard solution*

[Note—The relative retention times for nitrofurazone and nitrofurantoin are about 1.0 and 1.1, respectively.]

Suitability requirements

Resolution: NLT 2.0 between nitrofurazone and nitrofurantoin, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Peak identification solution*, *Standard solution*, and *Sample solution*

Calculate the percentage of each impurity in the portion of Nitrofurazone taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of each impurity from the *Sample solution*

r_S = peak response of nitrofurazone from the *Standard solution*

C_S = concentration of USP Nitrofurazone RS in the *Standard solution* (mg/mL)

C_U = concentration of Nitrofurazone in the *Sample solution* (mg/mL)

F = relative response factor (see *Table 1*)

Acceptance criteria: See *Table 1*. Disregard any peak less than 0.05%.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Nitrofurazone	1.0	—	—
Nitrofurfural diacetate	3.4	2.2	0.5
Nitrofurazone related compound A	6.0	1.6	0.5

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Any unspecified impurity	—	1.0	0.1
Total impurities	—	—	2.0

SPECIFIC TESTS

• **pH** ⟨791⟩

Sample solution: 1 g of Nitrofurazone in 100 mL of water. Shake for 15 min, allow the suspension to settle, and filter.

Acceptance criteria: 5.0–7.5

• **Loss on Drying** ⟨731⟩

Analysis: Dry at 105° for 1 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers, and avoid exposure to direct sunlight and to excessive heat.

• **USP Reference Standards** ⟨11⟩

USP Nitrofurantoin RS

USP Nitrofurazone RS

USP Nitrofurazone Related Compound A RS

5-Nitro-2-furfuraldazine.

$C_{10}H_6N_4O_6$ 278.18

USP Nitrofurfural Diacetate RS

(5-Nitrofuran-2-yl)methylene diacetate.

$C_9H_9NO_7$ 243.17

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

Topic/Question	Contact	Expert Committee
NITROFURAZONE	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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