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Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-B14191E3-CA8F-43AF-93E4-6515D346A25F_2_en-US
DOI: https://doi.org/10.31003/USPNF_M56800_02_01
DOI Ref: 3uy0m

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Nitrofurantoin Tablets

DEFINITION
Nitrofurantoin Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of nitrofurantoin ($C_8H_6N_4O_5$).

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197M⟩, *Infrared Spectroscopy*▲ (CN 1-May-2020)

Sample: Add 10 mL of 6 N acetic acid to an amount equivalent to 100 mg of nitrofurantoin from powdered Tablets. Boil for a few min, and filter while hot. Cool to room temperature, collect the precipitate of nitrofurantoin, and dry at 105° for 1 h.

Acceptance criteria: The IR absorption spectrum of a mineral oil dispersion of the precipitate from the *Sample* exhibits maxima only at the same wavelengths as that of a similar preparation of USP Nitrofurantoin RS.

• **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: Dissolve 6.8 g of monobasic potassium phosphate in 500 mL of water. Add about 30 mL of 1.0 N sodium hydroxide sufficient to adjust to a pH of 7.0, and dilute with water to 1 L.

Mobile phase: Acetonitrile and *Buffer* (12:88)

Internal standard solution: 1 mg/mL of acetanilide in water

Standard solution: 0.56 mg/mL of USP Nitrofurantoin RS prepared as follows. Dissolve 50 mg of USP Nitrofurantoin RS in 40.0 mL of dimethylformamide, and add 50.0 mL of *Internal standard solution*.

Sample solution: Nominally 0.56 mg/mL of nitrofurantoin prepared as follows. Mix an amount equivalent to 50 mg of nitrofurantoin from powdered Tablets (NLT 20) with 40.0 mL of dimethylformamide, and shake mechanically for 15 min. Add 50.0 mL of *Internal standard solution*, mix, and cool to room temperature. Pass a portion of the solution through a nylon filter having a pore size of 0.45-µm, discarding the first few mL of the filtrate.

Chromatographic system

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

[Note—Adjust the operating parameters so that the retention time of the nitrofurantoin peak is about 8 min and the peak height is about half full-scale.]

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; packing L1

Injection size: 5–10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 3.0 between acetanilide and nitrofurantoin

Relative standard deviation: NMT 2.0% determined from the ratio of the peak responses

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of nitrofurantoin ($C_8H_6N_4O_5$) in the portion of powdered Tablets taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = internal standard ratio (peak response of nitrofurantoin/peak response of acetanilide) from the *Sample solution*

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R_S = internal standard ratio (peak response of nitrofurantoin/peak response of acetanilide) from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: pH 7.2 phosphate buffer (see *Reagents, Indicators, and Solutions—Buffer Solutions*); 900 mL

Apparatus 1: 100 rpm

Times: 60 and 120 min

Standard stock solution: 0.1 mg/mL of USP Nitrofurantoin RS prepared as follows. Dissolve the required amount of USP Nitrofurantoin RS in 5% of the final volume of dimethylformamide. Dilute to final volume with *Medium*.

Standard solution: 10 µg/mL of USP Nitrofurantoin RS in *Medium* from *Standard stock solution*

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium*, if necessary.

Analysis

Samples: *Standard solution* and *Sample solution*

Analytical wavelength: 375 nm

Blank: *Medium*

Calculate the percentage of the labeled amount of nitrofurantoin ($C_8H_6N_4O_5$) dissolved:

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

A_U = absorbance from the *Sample solution*

A_S = absorbance from the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

V = volume of *Medium*, 900 mL

Tolerances: NLT 25% (Q) of the labeled amount of nitrofurantoin ($C_8H_6N_4O_5$) is dissolved in 60 min, and NLT 85% (Q) of the labeled amount of nitrofurantoin ($C_8H_6N_4O_5$) is dissolved in 120 min.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

• **Limit of Nitrofurazone**

Buffer: Proceed as directed in the *Assay*.

Mobile phase: Tetrahydrofuran and *Buffer* (10:90)

System suitability stock solution: 5.0 µg/mL each of USP Nitrofurazone RS and USP Nitrofurantoin RS in dimethylformamide

System suitability solution: 0.5 µg/mL each of USP Nitrofurazone RS and USP Nitrofurantoin RS in *Mobile phase* from *System suitability stock solution*

Standard stock solution: 5.0 µg/mL of USP Nitrofurazone RS in dimethylformamide.

Standard solution: Transfer 2.0 mL of the *Standard stock solution* into a glass-stoppered flask, and add 20.0 mL of water.

Sample solution: Transfer an equivalent to 100 mg of nitrofurantoin from powdered Tablets into a 25-mL, glass-stoppered flask. Add 2.0 mL of dimethylformamide, and shake for 5 min. Add 20.0 mL of water, mix, and allow to stand for 15 min. Pass a portion of the mixture through a nylon filter of 0.45-µm pore size.

Chromatographic system

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

[Note—Adjust the operating parameters so that the nitrofurazone peak has a retention time of about 10.5 min and its height is about 0.1 full-scale.]

Mode: LC

Detector: UV 375 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1.6 mL/min

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Injection size: 60–100 µL

System suitability

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

Suitability requirements

Resolution: NLT 4.0 between the nitrofurantoin and nitrofurazone peaks, *System suitability solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Acceptance criteria: The height of any peak from the *Sample solution* at a retention time corresponding to that of the main peak from the *Standard solution* is NMT the height of the main peak from the *Standard solution* (NMT 0.01%).

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, light-resistant containers.
- **USP Reference Standards** ⟨11⟩

USP Nitrofurantoin RS

USP Nitrofurazone RS

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

Topic/Question	Contact	Expert Committee
NITROFURANTOIN TABLETS	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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 35(1)

Current DocID: GUID-B14191E3-CA8F-43AF-93E4-6515D346A25F_2_en-US

DOI: https://doi.org/10.31003/USPNF_M56800_02_01

DOI ref: 3uy0m

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