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Nitrofurantoin Oral Suspension

DEFINITION

Nitrofurantoin Oral Suspension is a suspension of Nitrofurantoin in a suitable aqueous vehicle. It contains, in each 100 mL, NLT 460 mg and NMT 540 mg of nitrofurantoin ($C_8H_6N_4O_5$).

IDENTIFICATION

• **A. Infrared Absorption**

Sample solution: 10 mL of Oral Suspension in 15 mL of acetone

Analysis: Warm the *Sample solution* to 50°, with stirring, to coagulate the excipients. Filter, evaporate the acetone with the aid of a warm air blast nearly to dryness, add 10 mL of acetic acid, heat to boiling, and filter while hot. Cool the filtrate to room temperature. Filter the precipitated nitrofurantoin, and dry at 105° for 1 h.

Acceptance criteria: The IR absorption spectrum of a mineral oil dispersion of the precipitate obtained 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: 0.065 mg/mL of acetanilide in *Mobile phase*

Standard stock solution: 0.25 mg/mL of USP Nitrofurantoin RS prepared as follows. Transfer the required amount in suitable volumetric flask, and dissolve in 50% of the final volume of dimethylformamide and 20% of the final volume of water. Cool to room temperature, and dilute with dimethylformamide to volume.

Standard solution: Transfer 4.0 mL of *Standard stock solution* to a glass-stoppered flask, and add 15.0 mL of *Internal standard solution*.

Sample stock solution: Nominally 0.25 mg/mL of nitrofurantoin prepared as follows. Transfer a volume of Oral Suspension to a suitable volumetric flask, add 20% of the final volume of water, and mix. Add 50% of the final volume of dimethylformamide, and shake the flask for 20 min. Cool to room temperature, and dilute with dimethylformamide to volume. Centrifuge a portion of the solution, and use the supernatant to prepare the *Sample solution*.

Sample solution: Transfer 4.0 mL of *Sample stock solution* to a glass-stoppered flask, add 15.0 mL of *Internal standard solution*, and mix. Pass a portion of the solution through a 5-µm pore size polytef filter, 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 its peak height is about half-full scale.]

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1.2 mL/min

Injection size: 15 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 3.5 between the acetanilide and nitrofurantoin peaks

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the quantity per volume, in mg/100 mL, of the labeled amount of nitrofurantoin ($C_8H_6N_4O_5$) in the Oral Suspension taken:

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

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

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)

D = dilution factor, *Sample stock solution* to *Sample solution*, 9500

Acceptance criteria: 460–540 mg/100 mL of $C_8H_6N_4O_5$

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩**

For Oral Suspension packaged in single-unit containers: Meets the requirements

• **Deliverable Volume ⟨698⟩:**

For Oral Suspension packaged in multiple-unit containers: Meets the requirements

IMPURITIES

• **Limit of *N*-(Aminocarbonyl)-*N*-[([5-Nitro-2- Furanyl]Methylene)-Amino]Glycine (NF 250)**

Buffer and **Mobile phase:** Prepare as directed in the *Assay*.

Standard solution: 2.5 µg/mL of USP Nitrofurantoin Related Compound A RS in *Mobile phase*

Sample solution: Nominally 0.05 mg/mL of nitrofurantoin in *Mobile phase* from Oral Suspension. Centrifuge a portion of this solution. Pass a portion of the supernatant through a polytef filter having a 5-µm pore size, discarding the first few mL.

Chromatographic system

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

[Note—Adjust the operating parameters so that the NF 250 peak has a retention time of between 3 and 6 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: 1.2 mL/min

Injection size: 30–60 µL

Analysis

Samples: *Standard solution* and *Sample solution*

Acceptance criteria: The height of any peak appearing in 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 5.0%).

SPECIFIC TESTS

• **pH ⟨791⟩:** 4.5–6.5

ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards ⟨11⟩**

USP Nitrofurantoin RS

USP Nitrofurantoin Related Compound A RS

(*N*-(Aminocarbonyl)-*N*-[([5-nitro-2-furanyl]-methylene)-amino]glycine).

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

Topic/Question	Contact	Expert Committee
NITROFURANTOIN ORAL SUSPENSION	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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