- **Organic Impurities: Limit of Nitrofurazone**

Solution A: Prepare as directed in the *Assay*.

Mobile phase: Tetrahydrofuran and *Solution A* (1:9)

System suitability stock solution: 5.0 µg/mL each of nitrofurazone and nitrofurantoin in dimethylformamide

System suitability solution: *System suitability stock solution* and *Mobile phase* (1:10)

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, add 20.0 mL of water, and mix.

Sample solution: Transfer a portion of Capsule contents equivalent to 100 mg of nitrofurantoin 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*.)

Mode: LC

Detector: UV 375 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1.6 mL/min

Injection volume: 60–100 µL

System suitability

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

[Note—Adjust the operating parameters so that the nitrofurazone peak in the chromatogram of the *Standard solution* has a retention time of about 10.5 min and a height of about 0.1 full-scale.]

Suitability requirements

Resolution: NLT 4.0 between the nitrofurazone and nitrofurantoin 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% of nitrofurazone is found.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers, and store at controlled room temperature.
- **Labeling:** Capsules that contain the macrocrystalline form of nitrofurantoin are so labeled. When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used.
- **USP Reference Standards ⟨11⟩**

USP Nitrofurantoin RS

USP Nitrofurazone RS

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