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Nitrofurazone Ointment

» Nitrofurazone Ointment is Nitrofurazone in a suitable water-miscible base. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of nitrofurazone ($C_6H_6N_4O_4$).

[Note—Avoid exposure at all times to direct sunlight, excessive heat, strong fluorescent lighting, and alkaline materials.]

Packaging and storage—Preserve in tight, light-resistant containers. Avoid exposure to direct sunlight, strong fluorescent lighting, and excessive heat.

USP Reference standards ⟨11⟩—

USP Nitrofurazone RS

Completeness of solution—One g dissolves in 9 mL of water to form a clear solution.

Identification—Dissolve 400 mg of potassium hydroxide in a mixture of 9.5 mL of alcohol and 0.5 mL of methanol. Immediately before use, dilute with dimethylformamide to 100 mL. To 10 mL of this solution add a quantity of Ointment, equivalent to about 10 µg of nitrofurazone, and mix: a purple solution results.

Assay—[Note—Protect from light all solutions that contain nitrofurazone.]

Triethylamine buffer—Transfer 100 mL of triethylamine to a 1000-mL volumetric flask. Add about 800 mL of water, and cautiously add 80 mL of phosphoric acid. Mix, allow to cool to ambient temperature, dilute with water to volume, mix, and pass through a nylon filter having a 0.5-µm or finer porosity.

Mobile phase—Prepare a filtered and degassed mixture of water, acetonitrile, and *Triethylamine buffer* (790:200:10). Make any necessary adjustments (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Transfer about 50 mg of USP Nitrofurazone RS, accurately weighed, to a 50-mL low-actinic volumetric flask, add 10 mL of dimethylformamide, and swirl to dissolve. Dilute with alcohol to volume, and mix. Transfer 10.0 mL of this solution to a 100-mL low-actinic volumetric flask, dilute with alcohol to volume, and mix. Transfer 10.0 mL of this solution to a 100-mL low-actinic volumetric flask containing 15 mL of alcohol, dilute with water to volume, and mix. This solution contains about 0.01 mg of USP Nitrofurazone RS per mL.

Assay preparation—Transfer an accurately weighed portion of Ointment, equivalent to about 1 mg of nitrofurazone, to a 100-mL low-actinic volumetric flask. Add 0.2 mL of dimethylformamide and about 25 mL of alcohol, and sonicate for about 35 minutes. Dilute with water to volume, mix, and pass through a nylon filter having a 0.5-µm or finer porosity. Use the filtrate.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 365-nm detector and a 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the column efficiency determined from the nitrofurazone peak is not less than 1500 theoretical plates, and the relative standard deviation for replicate injections is not more than 2%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of nitrofurazone ($C_6H_6N_4O_4$) in the portion of Ointment taken by the formula:

$$100C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Nitrofurazone RS in the *Standard preparation;* and r_U and r_S are the nitrofurazone peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
NITROFURAZONE OINTMENT	Documentary Standards Support	SM12020 Small Molecules 1

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REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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