*Mobile phase*—Use variable mixtures of *Solution A* and *Solution B* as directed for *Chromatographic system*. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

*System suitability solution*—Dissolve suitable quantities of USP Fulvestrant System Suitability Mixture RS in methanol to obtain a solution containing about 10 mg of USP Fulvestrant System Suitability Mixture RS per mL.

*Standard preparation*—Dissolve an accurately weighed quantity of USP Fulvestrant RS in methanol to obtain a solution having a known concentration of about 10 mg per mL.

*Assay preparation*—Transfer about 100 mg of Fulvestrant, accurately weighed, to a 10-mL volumetric flask, dissolve in and dilute with methanol to volume, and mix.

*Chromatographic system* (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 225-nm detector and a 4.6-mm × 15-cm column that contains 3.5- µm packing L7. The flow rate is about 2 mL per minute. The column temperature is maintained at 40 °. The chromatograph is programmed as follows.

| Time (minutes) | *Solution A* (%) | *Solution B* (%) | Elution |
|---|---|---|---|
| 0–25 | 100 | 0 | isocratic |
| 25–55 | 100→0 | 0→100 | linear gradient |
| 55–65 | 0 | 100 | isocratic |
| 65–66 | 0→100 | 100→0 | linear gradient |
| 66–70 | 100 | 0 | equilibration |

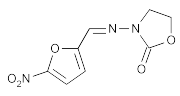
Chromatograph the *System suitability solution,* and record the peak responses as directed for *Procedure:* the relative retention times are about 1.1 for fulvestrant β-isomer and 1.0 for fulvestrant; the resolution, *R*, between fulvestrant and fulvestrant β-isomer is not less than 1.5; and the tailing factor for the fulvestrant peak is not more than 1.5. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the relative standard deviation for replicate injections is not more than 2.0%.

*Procedure*—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the fulvestrant peaks. Calculate the quantity, in mg, of $C_{32}H_{47}F_5O_3S$ in the portion of Fulvestrant taken by the formula:

$$CV(r_U / r_S)$$

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

## Furazolidone



$C_8H_7N_3O_5$ 225.16
2-Oxazolidinone, 3-[[(5-nitro-2-furanyl)methylene]amino]-.
3-[(5-Nitrofurfurylidene)amino]-2-oxazolidinone [67-45-8].

» Furazolidone contains not less than 97.0 percent and not more than 103.0 per cent of $C_8H_7N_3O_5$, calculated on the dried basis.

**Packaging and storage—**Preserve in tight, light-resistant containers, and avoid exposure to direct sunlight.

**USP Reference standards** ⟨11⟩**—**
USP Furazolidone RS

**Identification—**

**A:** *Infrared Absorption* ⟨197K⟩: previously dried.

**B:** *Ultraviolet Absorption* ⟨197U⟩—

*Solution:* 10 µg per mL.

**C:** Add about 50 mg to 10 mL of a freshly prepared mixture of dimethylformamide and alcoholic potassium hydroxide TS (9:1): the solution becomes purple, immediately changes to deep blue, and, upon standing for 10 minutes, again turns purple.

**Loss on drying** ⟨731⟩**—**Dry it at 100 ° for 1 hour: it loses not more than 1.0% of its weight.

**Residue on ignition** ⟨281⟩: not more than 0.25%.

**Assay—**Transfer about 100 mg of Furazolidone, accurately weighed, to a 250-mL volumetric flask, dilute with dimethylformamide to volume, and mix. Transfer 5.0 mL of this solution to a 250-mL volumetric flask, dilute with water to volume, and mix (assay solution). Similarly, dissolve a suitable quantity of USP Furazolidone RS, accurately weighed, in dimethylformamide to obtain a Standard stock solution having a known concentration of about 400 µg per mL. Transfer 5.0 mL of this stock solution to a 250-mL volumetric flask, dilute with water to volume, and mix (Standard solution). Concomitantly determine the absorbances of the assay solution and the Standard solution at the wavelength of maximum absorbance at about 367 nm, with a suitable spectrophotometer, using dimethylformamide solution (1 in 50) as the blank. Calculate the quantity, in mg, of $C_8H_7N_3O_5$ in the Furazolidone taken by the formula:

$$12.5C(A_U / A_S)$$

in which *C* is the concentration, in µg per mL, of USP Furazolidone RS in the Standard solution; and $A_U$ and $A_S$ are the absorbances of the assay solution and the Standard solution, respectively.

## Furazolidone Oral Suspension

» Furazolidone Oral Suspension is a suspension of Furazolidone in a suitable aqueous vehicle. It contains not less than 90.0 per cent and not more than 110.0 per cent of the labeled amount of furazolidone ($C_8H_7N_3O_5$).

**Packaging and storage—**Preserve in tight, light-resistant containers, and avoid exposure to excessive heat.

**USP Reference standards** ⟨11⟩**—**
USP Furazolidone RS

**Identification—**Add a quantity of Oral Suspension, equivalent to about 50 mg of furazolidone, to 10 mL of a freshly prepared mixture of dimethylformamide and alcoholic potassium hydroxide TS (9:1): the solution turns purple, immediately changes to deep blue, and, upon standing for 10 minutes, again turns purple.

**pH** ⟨791⟩: between 6.0 and 8.5.

**Assay—**Transfer an accurately measured volume of Oral Suspension, equivalent to about 160 mg of furazolidone, to a suitable flask. Add 5 mL of water, and mix. Transfer the mixture with the aid of dimethylformamide to a 1000-mL volumetric flask. Add about 500 mL of dimethylformamide, shake by mechanical means for 10 minutes, dilute with dimethylformamide to volume, and mix. Transfer 5.0 mL of this solution to a 100-mL volumetric flask, dilute with water to volume, and mix (assay solution). Similarly, dissolve a suitable quantity of USP Furazolidone RS, accurately weighed, in dimethylformamide to obtain a Standard stock solution having a known concentration of about 160 µg per mL. Transfer 5.0 mL of this stock solution