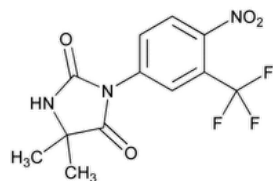


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Nilutamide



$C_{12}H_{10}F_3N_3O_4$ 317.22

2,4-Imidazolidinedione, 5,5-dimethyl-3-[4-nitro-3-(trifluoromethyl)phenyl]-;

5,5-Dimethyl-3-(α,α,α -trifluoro-4-nitro-*m*-tolyl)hydantoin;

5,5-Dimethyl-3-[4-nitro-3-(trifluoromethyl)phenyl]-imidazolidine-2,4-dione CAS RN[®]: 63612-50-0.

DEFINITION

Nilutamide contains NLT 98.0% and NMT 102.0% of nilutamide ($C_{12}H_{10}F_3N_3O_4$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197A or 197K ▲ (CN 1-May-2020)
- **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

[NOTE—Throughout the following procedures, protect the sample, the Reference Standard, and solutions containing them by conducting the procedures under subdued light or using low-actinic glassware.]

Buffer: 2.0 g/L of [monobasic potassium phosphate](#) in [water](#). Adjust with a solution of [1 N sodium hydroxide](#) in [water](#) to a pH of 7.5.

Mobile phase: [Acetonitrile](#) and *Buffer* (40:60)

Diluent: [Acetonitrile](#) and [water](#) (35:65)

Standard solution: 0.5 mg/mL of [USP Nilutamide RS](#) in *Diluent*

Sample solution: 0.5 mg/mL of Nilutamide in *Diluent*

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 267 nm

Column: 4.6-mm × 15-cm; 5-μm packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 20 μL

Run time: NLT 5 times the retention time of nilutamide

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of nilutamide ($C_{12}H_{10}F_3N_3O_4$) in the portion of Nilutamide taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of nilutamide from the *Sample solution*

r_S = peak response of nilutamide from the *Standard solution*

C_S = concentration of [USP Nilutamide RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#)

Analysis: Use a platinum crucible.

Acceptance criteria: NMT 0.1%

• ORGANIC IMPURITIES

Solution A: 2.0 g/L of [monobasic potassium phosphate](#) in [water](#). Adjust with a solution of [1 N sodium hydroxide](#) in [water](#) to a pH of 7.5.

Solution B: [Acetonitrile](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	55	45
8	55	45
30	30	70
31	55	45
45	55	45

Diluent: [Acetonitrile](#) and [water](#) (35:65)

System suitability solution: 0.04 mg/mL each of [USP Nilutamide RS](#) and [USP Flutamide Related Compound A RS](#) in *Diluent*

Standard solution: 0.002 mg/mL of [USP Nilutamide RS](#) in *Diluent*

Sample solution: 1.0 mg/mL of Nilutamide in *Diluent*

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 230 nm

Column: 4.6-mm × 15-cm; 5-μm packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 20 μL

System suitability

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

[NOTE—See [Table 2](#) for relative retention times.]

Suitability requirements

Resolution: NLT 3.0 between nilutamide and flutamide related compound A, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each individual impurity in the portion of Nilutamide taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$