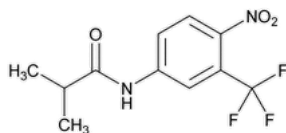


Status: Currently Official on 14-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-D0D03E9D-3491-4174-839B-DF962B4937D5_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M34200_04_01
 DOI Ref: gsi4q

© 2025 USPC
 Do not distribute

Flutamide



$C_{11}H_{11}F_3N_2O_3$ 276.21

Propanamide, 2-methyl-N-[4-nitro-3-trifluoromethyl)phenyl]-;

α,α -Trifluoro-2-methyl-4-nitro-*m*-propionotoluidide CAS RN®: 13311-84-7; UNII: 76W6J0943E.

DEFINITION

Flutamide contains NLT 98.0% and NMT 101.0% of flutamide ($C_{11}H_{11}F_3N_2O_3$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197M](#) ▲ (CN 1-MAY-2020)
- **B.** The retention time of the major peak from the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Mobile phase: Acetonitrile and water (45:55)

Diluent: Acetonitrile and water (20:80)

System suitability stock solution: 1 mg/mL of [USP o-Flutamide RS](#), prepared as follows. Dissolve the Standard in acetonitrile using 20% of the final volume. Sonicate to dissolve. Dilute with water to volume. Mix, and allow to warm to room temperature.

Standard solution: 0.2 mg/mL of [USP Flutamide RS](#), prepared as follows. Dissolve the Standard in acetonitrile using 20% of the final volume. Sonicate to dissolve. Dilute with water to volume. Mix, and allow to warm to room temperature.

System suitability solution: 10 µg/mL each of [USP o-Flutamide RS](#) and [USP Flutamide RS](#) in *Diluent* prepared from the *System suitability stock solution* and the *Standard solution*

Sample solution: 0.2 mg/mL of Flutamide, prepared as follows. Dissolve a previously dried sample in acetonitrile using 20% of the final volume. Sonicate to dissolve. Dilute with water to volume. Mix, and allow to warm to room temperature.

Chromatographic system

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

Mode: LC

Detector: UV 240 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: 25 ± 5°

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

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

[NOTE—For the relative retention times, see [Table 1](#).]

Suitability requirements

Resolution: NLT 6.0 between flutamide and o-flutamide, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 1.5%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of flutamide ($C_{11}H_{11}F_3N_2O_3$) in the portion of Flutamide taken:

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

r_U = peak area from the *Sample solution*

r_s = peak area from the *Standard solution*

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

C_u = concentration of Flutamide in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–101.0% on the dried basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• ORGANIC IMPURITIES

Mobile phase, Diluent, Standard solution, Sample solution, and Chromatographic system: Prepare as directed in the Assay.

System suitability stock solution: 1 mg/mL each of [USP o-Flutamide RS](#), [USP Flutamide Related Compound A RS](#), and [USP Flutamide Related Compound B RS](#), prepared as follows. Dissolve the Standards in acetonitrile using 20% of the final volume. Sonicate to dissolve. Dilute with water to volume. Mix, and allow to warm to room temperature.

System suitability solution: 10 µg/mL each of [USP o-Flutamide RS](#), [USP Flutamide Related Compound A RS](#), [USP Flutamide Related Compound B RS](#), and [USP Flutamide RS](#) in *Diluent*, prepared from the *System suitability stock solution* and *Standard solution*

Sensitivity solution: 0.1 µg/mL of [USP Flutamide RS](#) from the *Standard solution* in *Diluent*

System suitability

Samples: *System suitability solution* and *Sensitivity solution*

[NOTE—For the relative retention times, see [Table 1](#).]

Suitability requirements

Resolution: NLT 6.0 between flutamide and o-flutamide; NLT 2.0 between flutamide related compound A and flutamide related compound B, *System suitability solution*

Relative standard deviation: NMT 10.0% for flutamide, *Sensitivity solution*

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Flutamide taken:

$$\text{Result} = (r_u/r_T) \times (1/F) \times 100$$

r_u = peak area for each impurity

r_T = sum of all the peak responses

F = relative response factor (see [Table 1](#))

Acceptance criteria: See [Table 1](#).

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Flutamide related compound B ^a	0.42	1.06	0.2
Flutamide related compound A ^b	0.45	1.10	0.15
3-(Trifluoromethyl) aniline	0.63	1.10	0.2
Propionyl analog ^c	0.66	1.02	0.3
Desnitroflutamide ^d	0.80	1.95	0.2
o-Flutamide ^e	1.40	1.78	0.2
Flutamide	1.0	—	—
Any unknown impurity	—	1.0	0.05