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Flutamide Capsules

DEFINITION
Flutamide Capsules contain NLT 93.0% and NMT 107.0% of the labeled amount of flutamide ($C_{11}H_{11}F_3N_2O_3$).

IDENTIFICATION
- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution* as obtained in the *Assay*.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY
- **Procedure**

Diluent: Acetonitrile and water (50:50)

Mobile phase: Acetonitrile and water (45:55)

Standard stock solution: 0.5 mg/mL of USP Flutamide RS in *Diluent*

Standard solution: 0.2 mg/mL of USP Flutamide RS from the *Standard stock solution* in water

Sample stock solution: Nominally 0.5 mg/mL of flutamide prepared as follows. Remove the contents of NLT 20 Capsules, and mix. Transfer a portion of the powder, equivalent to 125 mg of flutamide, into a 250-mL volumetric flask. Add 180 mL of *Diluent* and shake the flask for 15 min. Dilute with *Diluent* to volume, and mix. Allow the insoluble material to settle. The concentration is equivalent to 0.5 mg/mL of flutamide.

Sample solution: Nominally 0.2 mg/mL of flutamide prepared as follows. Transfer 20.0 mL of the supernatant from the *Sample stock solution* into a 50-mL volumetric flask, dilute with water to volume, mix, and pass through a polytef membrane filter of 0.45-µm pore size.

Chromatographic system

(See *Chromatography (621), System Suitability*.)

Mode: LC

Detector: UV 240 nm. For *Identification B*, use a diode array detector in the range of 210–400 nm.

Column: 4.6-mm × 25-cm; packing L1

Column temperature: 25 ± 5°

Flow rate: 1.0 mL/min

Injection volume: 20 µL

Run time: About two times the retention time of flutamide

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of flutamide ($C_{11}H_{11}F_3N_2O_3$) in the portion of Capsules 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 = nominal concentration of flutamide in the *Sample solution* (mg/mL)

Acceptance criteria: 93.0%–107.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Medium: 2% sodium lauryl sulfate solution; 1000 mL

Apparatus 2: 75 rpm

Time: 60 min

Standard solution: A known concentration of USP Flutamide RS in *Medium*

Sample solution: Filter portions of the solution under test. Dilute with *Medium* as needed.

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy* ⟨857⟩.)

Mode: UV

Analytical wavelength: 306 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of flutamide ($C_{11}H_{11}F_3N_2O_3$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times D \times V \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

D = dilution factor for the *Sample solution*

V = volume of *Medium*, 1000 mL

L = label claim (mg/Capsule)

Tolerances: NLT 75% (Q) of the labeled amount of flutamide ($C_{11}H_{11}F_3N_2O_3$) is dissolved.

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

IMPURITIES

• **Organic Impurities**

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

Detector sensitivity solution: 0.2 µg/mL from the *Standard solution* in a mixture of acetonitrile and water (1:4)

System suitability

Sample: *Detector sensitivity solution*

Suitability requirements

Relative standard deviation: NMT 10.0% for flutamide

Analysis

Sample: *Sample solution*

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

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak area of each impurity from the *Sample solution*, excluding those where peak areas are less than those of the *Detector sensitivity solution*

r_T = sum of all the peak responses from the *Sample solution*

Acceptance criteria

Individual impurities: NMT 0.2% for any impurity having a relative retention time of 0.45; NMT 0.1% for any other impurity

Total impurities: NMT 0.3%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed, light-resistant containers.

• **USP Reference Standards** ⟨11⟩

USP Flutamide RS

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

Topic/Question	Contact	Expert Committee
FLUTAMIDE CAPSULES	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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