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Bicalutamide Tablets

DEFINITION

Bicalutamide Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of bicalutamide ($C_{18}H_{14}F_4N_2O_4S$).

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

Change to read:

• PROCEDURE

Mobile phase: [Acetonitrile](#), [tetrahydrofuran](#), and [water](#) (15:20:65)

System suitability stock solution: 0.8 mg/mL of [USP Bicalutamide RS](#) and 0.4 mg/mL of [USP Bicalutamide Related Compound B RS](#) in [tetrahydrofuran](#)

System suitability solution: 0.04 mg/mL of [USP Bicalutamide RS](#) and 0.02 mg/mL of [USP Bicalutamide Related Compound B RS](#) from the *System suitability stock solution* in *Mobile phase*

Standard stock solution: 0.8 mg/mL of [USP Bicalutamide RS](#) in [tetrahydrofuran](#)

Standard solution: 0.04 mg/mL of [USP Bicalutamide RS](#) from the *Standard stock solution* in *Mobile phase*

Sample stock solution: ▲Nominally ▲ (IRA 1-Sep-2023) 0.5 mg/mL of bicalutamide ▲from Tablets ▲ (IRA 1-Sep-2023) in [tetrahydrofuran](#) prepared as follows. Transfer an equivalent to 50 mg of bicalutamide from finely powdered Tablets (NLT 20) into a 100-mL volumetric flask. Add 50 mL of [tetrahydrofuran](#), and sonicate for NLT 10 min to complete dissolution. Allow to cool to room temperature, and dilute with [tetrahydrofuran](#) to volume. Pass through a suitable filter of 0.45-μm pore size.

Sample solution: ▲Nominally ▲ (IRA 1-Sep-2023) 0.04 mg/mL of bicalutamide from the *Sample stock solution* in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 270 nm. For *Identification B*, use a diode array detector in the range of 190–400 nm.

Column: 5-mm × 12.5-cm; 3-μm packing [L1](#)

Column temperature: 50°

Flow rate: 1.5 mL/min

Injection volume: 10 μL

▲**Run time:** NLT 1.5 times the retention time of bicalutamide ▲ (IRA 1-Sep-2023)

System suitability

Samples: *System suitability solution* ▲ and *Standard solution* ▲ (IRA 1-Sep-2023)

[NOTE—The relative retention times for bicalutamide and bicalutamide related compound B are 1.0 and 1.1, respectively.]

Suitability requirements

Resolution: ▲NLT 2.0 ▲ (IRA 1-Sep-2023) between bicalutamide and bicalutamide related compound B ▲, *System suitability solution* ▲ (IRA 1-Sep-2023)

Tailing factor: ▲NMT 1.2, *Standard solution* ▲ (IRA 1-Sep-2023)

Relative standard deviation: NMT 1.0% ▲, *Standard solution* ▲ (IRA 1-Sep-2023)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of bicalutamide ($C_{18}H_{14}F_4N_2O_4S$) in the portion of Tablets taken:

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

r_U = peak area ▲ of bicalutamide ▲ (IRA 1-Sep-2023) from the *Sample solution*

r_s = peak area Δ of bicalutamide Δ (IRA 1-Sep-2023) from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#).

Test 1

Medium: Δ 10 mg/mL of Δ (IRA 1-Sep-2023) [sodium lauryl sulfate](#) in [water](#); 1000 mL

Apparatus 2: 50 rpm

Time: 45 min

Standard solution: 0.05 mg/mL of [USP Bicalutamide RS](#) in *Medium* prepared as follows. Transfer an appropriate amount of [USP Bicalutamide RS](#) to a suitable volumetric flask, dissolve in [tetrahydrofuran](#) equivalent to 1% of the final volume, and dilute with *Medium* to volume.

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV

Analytical wavelength: 270 nm

Δ Path length: 0.1 cm Δ (IRA 1-Sep-2023)

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of bicalutamide ($C_{18}H_{14}F_4N_2O_4S$) dissolved:

$$\text{Result} = (A_u/A_s) \times C_s \times V \times (1/L) \times 100$$

A_u = absorbance of the *Sample solution*

A_s = absorbance of the *Standard solution*

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

V = volume of *Medium* (mL)

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of bicalutamide ($C_{18}H_{14}F_4N_2O_4S$) is dissolved.

Test 2: If the product complies with this test, the labeling indicates that the product meets USP *Dissolution Test 2*.

Δ Medium: 10 mg/mL of [sodium lauryl sulfate](#) in [water](#); 1000 mL

Apparatus 2: 50 rpm

Time: 45 min

Standard solution: 0.05 mg/mL of [USP Bicalutamide RS](#) in *Medium* prepared as follows. Transfer an appropriate amount of [USP Bicalutamide RS](#) to a suitable volumetric flask, dissolve in [tetrahydrofuran](#) equivalent to 1% of the final volume, and dilute with *Medium* to volume.

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV

Analytical wavelength: 270 nm

Path length: 0.1 cm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of bicalutamide ($C_{18}H_{14}F_4N_2O_4S$) dissolved:

$$\text{Result} = (A_u/A_s) \times C_s \times V \times (1/L) \times 100$$

A_u = absorbance of the *Sample solution*