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Anastrozole Tablets

DEFINITION

Anastrozole Tablets contain NLT 90% and NMT 110% of the labeled amount of anastrozole ($C_{17}H_{19}N_5$).

IDENTIFICATION

Change to read:

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

Sample: Transfer the finely ground Tablet powder containing 8 mg of anastrozole into a suitable container. Add 10 mL of [diethyl ether](#) and sonicate for 5 min. Aspirate the supernatant and pass through a nylon filter of 0.45- μ m pore size into another suitable container containing 400 mg of [potassium bromide](#). Evaporate the mixture to dryness under nitrogen. Further dry it under vacuum at 50° for 1 h. Add an additional 400 mg of potassium bromide for preparation of pellet and analysis.

Acceptance criteria: The spectrum obtained from the *Sample* shows bands at approximately 2235, 1606, 1500, 1359, 1205, 1137, 1013, and 875 cm^{-1} , similar to the spectrum from the Reference Standard similarly obtained.

- **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

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

Diluent: [Acetonitrile](#) and [water](#) (50:50)

Standard solution: 40 μ g/mL of [USP Anastrozole RS](#) in *Diluent*. Sonication may be used to aid dissolution.

Sample solution: Nominally equivalent to 40 μ g/mL of anastrozole in *Diluent*, prepared as follows. Transfer NLT 10 Tablets to a suitable volumetric flask. Add 40% of the flask volume of [water](#), and shake on a rotary shaker for 10 min to disintegrate the Tablets. Add 40% of the flask volume of [acetonitrile](#), and sonicate for 15 min with intermittent shaking, maintaining the sonicator temperature at 25°. Dilute with *Diluent* to volume. Centrifuge a portion of the solution at 3500 rpm for 10 min, and use the clear solution for analysis.

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm $\times$ 15-cm; 5- μ m packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 20 μ L

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of anastrozole ($C_{17}H_{19}N_5$) in the portion of Tablets 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 Anastrozole RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90%–110%

PERFORMANCE TESTS• [DISSOLUTION \(711\)](#)**Test 1****Medium:** [Water](#); 900 mL, deaerated**Apparatus 2:** 50 rpm**Time:** 15 min**Mobile phase:** [Acetonitrile](#) and [water](#) (40:60)**Diluent:** [Acetonitrile](#) and [water](#) (50:50)**Standard stock solution:** 0.2 mg/mL of [USP Anastrozole RS](#) in *Diluent***Standard solution:** Dilute the *Standard stock solution* with *Medium* to obtain a final concentration of $(L/1000)$ mg/mL, where L is the label claim in mg/Tablet.**Sample solution:** Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size. Discard the first few mL of the filtrate.**Chromatographic system**(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 215 nm**Column:** 4.6-mm $\times$ 15-cm; 5- μ m packing [L1](#)**Flow rate:** 1 mL/min**Injection volume:** 50 μ L**System suitability****Sample:** *Standard solution***Suitability requirements****Tailing factor:** NMT 2.0**Relative standard deviation:** NMT 2.0%**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of anastrozole ($C_{17}H_{19}N_5$) dissolved:

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

 r_U = peak response from the *Sample solution* r_S = peak response from the *Standard solution* C_S = concentration of the *Standard solution* (mg/mL) L = label claim (mg/Tablet) V = volume of *Medium*, 900 mL**Tolerances:** NLT 80% (Q) of the labeled amount of anastrozole ($C_{17}H_{19}N_5$) is dissolved.**Test 2:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.**Medium:** [Water](#); 1000 mL, deaerated**Apparatus 2:** 50 rpm**Time:** 15 min**Mobile phase:** [Acetonitrile](#), [trifluoroacetic acid](#), and [water](#) (300:1:700)**Standard stock solution:** 0.2 mg/mL of [USP Anastrozole RS](#) prepared as follows. Transfer [USP Anastrozole RS](#) into a suitable volumetric flask and add [acetonitrile](#) equivalent to 8% of the final volume. Sonicate to dissolve and dilute with [water](#) to volume.**Standard solution:** Dilute the *Standard stock solution* with *Medium* to obtain a final concentration of $(L/1000)$ mg/mL, where L is the label claim in mg/Tablet.**Sample solution:** Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size. Discard the first few mL of the filtrate.**Chromatographic system**(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 215 nm**Column:** 3.2-mm $\times$ 10-cm; 5- μ m packing [L42](#)**Flow rate:** 0.75 mL/min**Injection volume:** 100 μ L**System suitability****Sample:** *Standard solution***Suitability requirements**