Anastrozole Tablets

アナストロゾール錠

Anastrozole Tablets contain not less than 95.0% and not more than 105.0% of the labeled amount of anastrozole ($C_{17}H_{19}N_5$: 293.37).

Method of preparation Prepare as directed under Tablets, with Anastrozole.

Identification Powder 8 tablets of Anastrozole Tablets, add 10 mL of diethyl ether, sonicate, and filter through a membrane filter with a pore size not exceeding 0.45 μm. To the filtrate add 0.40 g of potassium bromide for infrared spectrophotometry, and evaporate the diethyl ether. Determine the infrared absorption spectrum of the residue as directed in the potassium bromide disk method under Infrared Spectrophotometry <*2.25*>: it exhibits absorption at the wave numbers of about 3100 cm^{-1}, 2980 cm^{-1}, 2240 cm^{-1}, 1606 cm^{-1}, 1502 cm^{-1}, 1359 cm^{-1}, 1206 cm^{-1}, 1139 cm^{-1}, 876 cm^{-1}, 763 cm^{-1}, 713 cm^{-1} and 680 cm^{-1}.

Uniformity of dosage units <*6.02*> Perform the test according to the following method: it meets the requirement of the Content uniformity test.

To 1 tablet of Anastrozole Tablets add 8 mL of a mixture of water, acetonitrile for liquid chromatography and trifluoracetic acid (1000:1000:1), sonicate, and shake thoroughly until the tablet is completely disintegrated. Add a mixture of water, acetonitrile for liquid chromatography and trifluoracetic acid (1000:1000:1) to make exactly V mL so that each mL contains about 0.1 mg of anastrozole ($C_{17}H_{19}N_5$). Filter this solution through a membrane filter with a pore size not exceeding 0.45 μm, discard 3 mL of the first filtrate, and use the subsequent filtrate as the sample solution. Then, proceed as directed in the Assay.

Amount (mg) of anastrozole ($C_{17}H_{19}N_5$)
$= M_S \times A_T / A_S \times V / 500$

M_S: Amount (mg) of Anastrozole RS taken

Dissolution <*6.10*> When the test is performed at 50 revolutions per minute according to the Paddle method, using 1000 mL of water as the dissolution medium, the dissolution rate in 15 minutes of Anastrozole Tablets is not less than 80%.

Start the test with 1 tablet of Anastrozole Tablets, withdraw 10 mL of the medium at the specified minute after starting the test, and filter through a membrane filter with a pore size not exceeding 0.45 μm. Discard not less than 3 mL of the first filtrate, pipet V mL of the subsequent filtrate, add water to make exactly V' mL so that each mL contains about 1.0 μg of anastrozole ($C_{17}H_{19}N_5$), and use this solution as the sample solution. Separately, weigh accurately about 50 mg of Anastrozole RS, add 20 mL of acetonitrile for liquid chromatography, sonicate, and add water to make exactly 250 mL. Pipet 5 mL of this solution, add water to make exactly 100 mL. Pipet 10 mL of this solution, add water to make exactly 100 mL, and use this solution as the standard solution. Perform the test with exactly 100 μL each of the sample solution and standard solution as directed under Liquid Chromatography <*2.01*> according to the following conditions, and determine the peak areas, A_T and A_S, of anastrozole in each solution.

Dissolution rate (%) with respect to the labeled amount of anastrozole ($C_{17}H_{19}N_5$)
$= M_S \times A_T / A_S \times V' / V \times 1 / C \times 2$

M_S: Amount (mg) of Anastrozole RS taken
C: Labeled amount (mg) of anastrozole ($C_{17}H_{19}N_5$) in 1 tablet

Operating conditions—
Detector, column and column temperature: Proceed as directed in the operating conditions in the Assay under Anastrozole.
Mobile phase: A mixture of water, acetonitrile for liquid chromatography and trifluoracetic acid (700:300:1).
Flow rate: Adjust so that the retention time of anastrozole is about 7 minutes.
System suitability—
System performance: To 15 mg of methyl parahydoxybenzoate and 50 mg of Anastrozole RS, add 20 mL of acetonitrile for liquid chromatography, sonicate, and add water to make 250 mL. To 5 mL of this solution, add water to make 100 mL. To 10 mL of this solution add water to make 100 mL, and use this solution as the solution for system suitability test. When the procedure is run with 100 μL of the solution for system suitability test under the above operating conditions, methyl parahydoxybenzoate and anastrozole are eluted in this order with the resolution between these peaks being not less than 4.
System repeatability: When the test is repeated 6 times with 100 μL of the solution for system suitability test under the above operating conditions, the relative standard deviation of the peak area of anastrozole is not more than 1.5%.

Assay Weigh accurately the mass of not less than 20 tablets of Anastrozole Tablets, and powder. Weigh accurately a portion of the powder, equivalent to about 10 mg of anastrozole ($C_{17}H_{19}N_5$), add 80 mL of a mixture of water, acetonitrile for liquid chromatography and trifluoracetic acid (1000:1000:1), sonicate, and add a mixture of water, acetonitrile for liquid chromatography and trifluoracetic acid (1000:1000:1) to make exactly 100 mL. Filter this solution

through a membrane filter with a pore size not exceeding 0.45 μm, discard 3 mL of the first filtrate, and use the subsequent filtrate as the sample solution. Separately, weigh accurately about 50 mg of Anastrozole RS, add 50 mL of a mixture of water, acetonitrile for liquid chromatography and trifluoracetic acid (1000:1000:1), sonicate, and add a mixture of water, acetonitrile for liquid chromatography and trifluoracetic acid (1000:1000:1) to make exactly 100 mL. Pipet 10 mL of this solution, add a mixture of water, acetonitrile for liquid chromatography and trifluoracetic acid (1000:1000:1) to make exactly 50 mL, and use this solution as the standard solution. Perform the test with exactly 10 μL each of the sample solution and standard solution as directed under Liquid Chromatography <2.01> according to the following conditions, and determine the peak areas, A_T and A_S, of anastrozole in each solution.

$$\text{Amount (mg) of anastrozole } (C_{17}H_{19}N_5) = M_S \times A_T / A_S \times 1/5$$

M_S: Amount (mg) of Anastrozole RS taken

Operating conditions—

Detector, column and column temperature: Proceed as directed in the operating conditions in the Assay under Anastrozole.

Mobile phase: A mixture of water, methanol for liquid chromatography, acetonitrile for liquid chromatography and trifluoroacetic acid (7000:2000:1000:7).

Flow rate: Adjust so that the retention time of anastrozole is about 15 minutes.

System suitability—

System performance: To 30 mg of ethyl parahydoxybenzoate and 50 mg of Anastrozole RS, add 50 mL of a mixture of water, acetonitrile for liquid chromatography and trifluoracetic acid (1000:1000:1), sonicate, and add a mixture of water, acetonitrile for liquid chromatography and trifluoracetic acid (1000:1000:1) to make 100 mL. To 10 mL of this solution add a mixture of water, acetonitrile for liquid chromatography and trifluoracetic acid (1000:1000:1) to make 50 mL, and use this solution as the solution for system suitability test. When the procedure is run with 10 μL of the solution for system suitability test under the above operating conditions, ethyl parahydoxybenzoate and anastrozole are eluted in this order with the resolution between these peaks being not less than 4.

System repeatability: When the test is repeated 6 times with 10 μL of the solution for system suitability test under the above operating conditions, the relative standard deviation of the peak area of anastrozole is not more than 1.5%.

Containers and storage Containers—Tight containers.

Add the following to 9.01 Reference Standards (1):

Anastrozole RS

Add the following to 9.42 Solid Supports/Column Packings for Chromatography:

Octadecylsilyl and octylsilyl groups bound porous silica gel for liquid chromatography A porous silica gel bound with octadecylsilyl and octylsilyl groups, prepared for liquid chromatography.