

1 Anastrozole Tablets

2 アナストロゾール錠

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4 Anastrozole Tablets contain not less than 95.0%
5 and not more than 105.0% of the labeled amount of
6 anastrozole (C₁₇H₁₉N₅; 293.37).

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

9 **Identification** Powder 8 tablets of Anastrozole Tablets,
10 add 10 mL of diethyl ether, sonicate, and filter through a
11 membrane filter with a pore size not exceeding 0.45 μm. To
12 the filtrate add 0.40 g of potassium bromide for infrared
13 spectrophotometry, and evaporate the diethyl ether. Deter-
14 mine the infrared absorption spectrum of the residue as di-
15 rected in the potassium bromide disk method under Infrared
16 Spectrophotometry <2.25>: it exhibits absorption at the
17 wave numbers of about 3100 cm⁻¹, 2980 cm⁻¹, 2240 cm⁻¹,
18 1606 cm⁻¹, 1502 cm⁻¹, 1359 cm⁻¹, 1206 cm⁻¹, 1139 cm⁻¹,
19 876 cm⁻¹, 763 cm⁻¹, 713 cm⁻¹ and 680 cm⁻¹.

20 **Uniformity of dosage units** <6.02> Perform the test ac-
21 cording to the following method: it meets the requirement
22 of the Content uniformity test.

23 To 1 tablet of Anastrozole Tablets add 8 mL of a mixture
24 of water, acetonitrile for liquid chromatography and trifluo-
25 racetic acid (1000:1000:1), sonicate, and shake thoroughly
26 until the tablet is completely disintegrated. Add a mixture of
27 water, acetonitrile for liquid chromatography and trifluo-
28 racetic acid (1000:1000:1) to make exactly V mL so that
29 each mL contains about 0.1 mg of anastrozole (C₁₇H₁₉N₅).
30 Filter this solution through a membrane filter with a pore
31 size not exceeding 0.45 μm, discard 3 mL of the first filtrate,
32 and use the subsequent filtrate as the sample solution. Then,
33 proceed as directed in the Assay.

$$34 \quad \text{Amount (mg) of anastrozole (C}_{17}\text{H}_{19}\text{N}_5\text{)} \\ 35 \quad = M_S \times A_T/A_S \times V/500$$

36 M_S : Amount (mg) of Anastrozole RS taken

37 **Dissolution** <6.10> When the test is performed at 50 rev-
38 olutions per minute according to the Paddle method, using
39 1000 mL of water as the dissolution medium, the dissolu-
40 tion rate in 15 minutes of Anastrozole Tablets is not less
41 than 80%.

42 Start the test with 1 tablet of Anastrozole Tablets, with-
43 draw 10 mL of the medium at the specified minute after
44 starting the test, and filter through a membrane filter with a
45 pore size not exceeding 0.45 μm. Discard not less than 3
46 mL of the first filtrate, pipet V mL of the subsequent filtrate,
47 add water to make exactly V' mL so that each mL contains

48 about 1.0 μg of anastrozole (C₁₇H₁₉N₅), and use this solution
49 as the sample solution. Separately, weigh accurately about
50 50 mg of Anastrozole RS, add 20 mL of acetonitrile for
51 liquid chromatography, sonicate, and add water to make
52 exactly 250 mL. Pipet 5 mL of this solution, add water to
53 make exactly 100 mL. Pipet 10 mL of this solution, add
54 water to make exactly 100 mL, and use this solution as the
55 standard solution. Perform the test with exactly 100 μL each
56 of the sample solution and standard solution as directed
57 under Liquid Chromatography <2.01> according to the fol-
58 lowing conditions, and determine the peak areas, A_T and A_S,
59 of anastrozole in each solution.

60 Dissolution rate (%) with respect to the labeled amount of
61 anastrozole (C₁₇H₁₉N₅)

$$62 \quad = M_S \times A_T/A_S \times V'/V \times 1/C \times 2$$

63 M_S : Amount (mg) of Anastrozole RS taken

64 C : Labeled amount (mg) of anastrozole (C₁₇H₁₉N₅) in 1
65 tablet

66 **Operating conditions**—

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

70 Mobile phase: A mixture of water, acetonitrile for liquid
71 chromatography and trifluoroacetic acid (700:300:1).

72 Flow rate: Adjust so that the retention time of anastrozole
73 is about 7 minutes.

74 **System suitability**—

75 System performance: To 15 mg of methyl para-
76 hydroxybenzoate and 50 mg of Anastrozole RS, add 20 mL
77 of acetonitrile for liquid chromatography, sonicate, and add
78 water to make 250 mL. To 5 mL of this solution, add water
79 to make 100 mL. To 10 mL of this solution add water to
80 make 100 mL, and use this solution as the solution for sys-
81 tem suitability test. When the procedure is run with 100 μL
82 of the solution for system suitability test under the above
83 operating conditions, methyl parahydroxybenzoate and anas-
84 trozole are eluted in this order with the resolution between
85 these peaks being not less than 4.

86 System repeatability: When the test is repeated 6 times
87 with 100 μL of the solution for system suitability test under
88 the above operating conditions, the relative standard devia-
89 tion of the peak area of anastrozole is not more than 1.5%.

90 **Assay** Weigh accurately the mass of not less than 20 tab-
91 lets of Anastrozole Tablets, and powder. Weigh accurately a
92 portion of the powder, equivalent to about 10 mg of anas-
93 trozole (C₁₇H₁₉N₅), add 80 mL of a mixture of water, ace-
94 tonitrile for liquid chromatography and trifluoroacetic acid
95 (1000:1000:1), sonicate, and add a mixture of water, ace-
96 tonitrile for liquid chromatography and trifluoroacetic acid
97 (1000:1000:1) to make exactly 100 mL. Filter this solution

98 through a membrane filter with a pore size not exceeding
 99 0.45 μm , discard 3 mL of the first filtrate, and use the sub-
 100 sequent filtrate as the sample solution. Separately, weigh
 101 accurately about 50 mg of Anastrozole RS, add 50 mL of a
 102 mixture of water, acetonitrile for liquid chromatography and
 103 trifluoroacetic acid (1000:1000:1), sonicate, and add a mix-
 104 ture of water, acetonitrile for liquid chromatography and
 105 trifluoroacetic acid (1000:1000:1) to make exactly 100 mL.
 106 Pipet 10 mL of this solution, add a mixture of water, ace-
 107 tonitrile for liquid chromatography and trifluoroacetic acid
 108 (1000:1000:1) to make exactly 50 mL, and use this solution
 109 as the standard solution. Perform the test with exactly 10 μL
 110 each of the sample solution and standard solution as di-
 111 rected under Liquid Chromatography <2.01> according to
 112 the following conditions, and determine the peak areas, A_T
 113 and A_S , of anastrozole in each solution.

$$\begin{aligned} 114 \quad & \text{Amount (mg) of anastrozole (C}_{17}\text{H}_{19}\text{N}_5\text{)} \\ 115 \quad & = M_S \times A_T / A_S \times 1/5 \end{aligned}$$

116 M_S : Amount (mg) of Anastrozole RS taken

117 *Operating conditions—*

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

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

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

126 *System suitability—*

127 System performance: To 30 mg of ethyl parahydroxyben-
 128 zoate and 50 mg of Anastrozole RS, add 50 mL of a mixture
 129 of water, acetonitrile for liquid chromatography and trifluo-
 130 racetic acid (1000:1000:1), sonicate, and add a mixture of
 131 water, acetonitrile for liquid chromatography and trifluo-
 132 racetic acid (1000:1000:1) to make 100 mL. To 10 mL of
 133 this solution add a mixture of water, acetonitrile for liquid
 134 chromatography and trifluoroacetic acid (1000:1000:1) to
 135 make 50 mL, and use this solution as the solution for system
 136 suitability test. When the procedure is run with 10 μL of the
 137 solution for system suitability test under the above operating
 138 conditions, ethyl parahydroxybenzoate and anastrozole are
 139 eluted in this order with the resolution between these peaks
 140 being not less than 4.

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

145 **Containers and storage** Containers—Tight containers.

146 **Add the following to 9.01 Reference**
 147 **Standards (1):**

148 **Anastrozole RS**

149 **Add the following to 9.42 Solid Sup-**
 150 **ports/Column Packings for Chromatography:**

151 **Octadecylsilyl and octylsilyl groups bound porous sil-**
 152 **ica gel for liquid chromatography** A porous silica gel
 153 bound with octadecylsilyl and octylsilyl groups, prepared
 154 for liquid chromatography.