

1 Cloperastine Fendizoate Tablets

2 クロベラスチンフェンジゾ酸塩錠

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4 Cloperastine Fendizoate Tablets contain not less
5 than 95.0% and not more than 105.0% of the labeled
6 amount of cloperastine fendizoate
7 ($C_{20}H_{24}ClNO \cdot C_{20}H_{14}O_4$; 648.19).

8 **Method of preparation** Prepare as directed under Tab-
9 lets, with Cloperastine Fendizoate.

10 **Identification** To a quantity of powdered Cloperastine
11 Fendizoate Tablets, equivalent to 1.5 mg of Cloperastine
12 Fendizoate, add methanol, shake thoroughly, add methanol
13 to make 100 mL, and filter. Determine the absorption spec-
14 trum of the filtrate as directed under Ultraviolet-visible
15 Spectrophotometry <2.24>: it exhibits maxima between 248
16 nm and 252 nm, and between 282 nm and 286 nm.

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

20 To 1 tablet of Cloperastine Fendizoate Tablets add ex-
21 actly $V/10$ mL of the internal standard solution, add the
22 mobile phase, shake vigorously until the tablet is disinte-
23 grated, add the mobile phase to make V mL so that each mL
24 contains about 88 μg of cloperastine fendizoate
25 ($C_{20}H_{24}ClNO \cdot C_{20}H_{14}O_4$), and filter through a membrane fil-
26 ter with a pore size not exceeding 0.45 μm . Discard the first
27 10 mL of the filtrate, and use the subsequent filtrate as the
28 sample solution. Then, proceed as directed in the Assay.

29 Amount (mg) of cloperastine fendizoate ($C_{20}H_{24}ClNO \cdot$
30 $C_{20}H_{14}O_4$)

$$31 = M_S \times Q_T / Q_S \times V / 250$$

32 M_S : Amount (mg) of cloperastine fendizoate for assay
33 taken

34 **Internal standard solution**— A solution of ethyl parahy-
35 droxybenzoate in the mobile phase (3 in 2000).

36 **Dissolution** <6.10> When the test is performed at 50 rev-
37 olutions per minute according to the Paddle method, using
38 900 mL of 1st fluid for dissolution test as the dissolution
39 medium, the dissolution rate in 90 minutes of Cloperastine
40 Fendizoate Tablets is not less than 75%.

41 Start the test with 1 tablet of Cloperastine Fendizoate
42 Tablets, withdraw not less than 20 mL of the medium at the
43 specified minute after starting the test, and filter through a
44 membrane filter with a pore size not exceeding 0.45 μm .
45 Discard the first 10 mL of the filtrate, pipet V mL of the
46 subsequent filtrate, add 1st fluid for dissolution test to make
47 exactly V' mL so that each mL contains about 4.9 μg of

48 cloperastine fendizoate ($C_{20}H_{24}ClNO \cdot C_{20}H_{14}O_4$), and use
49 this solution as the sample solution. Separately, weigh ac-
50 curately about 25 mg of cloperastine fendizoate for assay,
51 previously dried at 105°C for 3 hours, and dissolve in meth-
52 anol to make exactly 200 mL. Pipet 4 mL of this solution,
53 add 1st fluid for dissolution test to make exactly 100 mL,
54 and use this solution as the standard solution. Perform the
55 test with exactly 10 μL each of the sample solution and
56 standard solution as directed under Liquid Chromatog-
57 raphy <2.01>, and determine the peak areas, A_T and A_S , of
58 cloperastine in each solution.

59 Dissolution rate (%) with respect to the labeled amount of
60 cloperastine fendizoate ($C_{20}H_{24}ClNO \cdot C_{20}H_{14}O_4$)

$$61 = M_S \times A_T / A_S \times V' / V \times 1 / C \times 18$$

62 M_S : Amount (mg) of cloperastine fendizoate for assay
63 taken

64 C : Labeled amount (mg) of cloperastine fendizoate
65 ($C_{20}H_{24}ClNO \cdot C_{20}H_{14}O_4$) in 1 tablet

66 **Operating conditions**—

67 Proceed as directed in the operating conditions in the
68 Assay.

69 **System suitability**—

70 System performance: When the procedure is run with 10
71 μL of the standard solution under the above operating
72 conditions, fendizoic acid and cloperastine are eluted in this
73 order with the resolution between these peaks being not less
74 than 6.

75 System repeatability: When the test is repeated 6 times
76 with 10 μL of the standard solution under the above
77 operating conditions, the relative standard deviation of the
78 peak area of cloperastine is not more than 2.0%.

79 **Assay** Weigh accurately the mass of not less than 20 tab-
80 lets of Cloperastine Fendizoate Tablets, and powder.
81 Weigh accurately a portion of the powder, equivalent to
82 about 4.4 mg of cloperastine fendizoate
83 ($C_{20}H_{24}ClNO \cdot C_{20}H_{14}O_4$), add exactly 5 mL of the internal
84 standard solution, add 20 mL of the mobile phase, shake
85 vigorously for 10 minutes, then add the mobile phase to
86 make 50 mL, and filter through a membrane filter with a
87 pore size not exceeding 0.45 μm . Discard the first 10 mL
88 of the filtrate and use the subsequent filtrate as the sample
89 solution. Separately, weigh accurately about 22 mg of clop-
90 erastine fendizoate for assay, previously dried at 105°C for
91 3 hours, and dissolve in the mobile phase to make exactly
92 50 mL. Pipet 10 mL of this solution, add exactly 5 mL of
93 the internal standard solution, add the mobile phase to make
94 50 mL, and use this solution as the standard solution. Per-
95 form the test with exactly 20 μL each of the sample solution

96 and standard solution as directed under Liquid Chromatog-
97 raphy <2.01>, and calculate the ratios, Q_T and Q_S , of the
98 peak area of cloperastine to that of the internal standard.

99 Amount (mg) of cloperastine fendizoate
100 ($C_{20}H_{24}ClNO.C_{20}H_{14}O_4$)
101 $=M_S \times Q_T/Q_S \times 1/5$

102 M_S : Amount (mg) of cloperastine fendizoate for assay
103 taken

104 *Internal standard solution*— A solution of ethyl parahy-
105 droxybenzoate in the mobile phase (3 in 2000).

106 *Operating conditions*—

107 Detector: An ultraviolet absorption photometer
108 (wavelength: 226 nm).

109 Column: A stainless steel column 4.6 mm in inside
110 diameter and 15 cm in length, packed with
111 octadecylsilanized silica gel for liquid chromatography (5
112 μm in particle diameter).

113 Column temperature: A constant temperature of about
114 25°C.

115 Mobile phase: A mixture of 0.1 mol/L potassium
116 dihydrogen phosphate TS, acetonitrile for liquid
117 chromatography and perchloric acid (400:320:1).

118 Flow rate: Adjust so that the retention time of
119 cloperastine is about 8 minutes.

120 *System suitability*—

121 System performance: When the procedure is run with 20
122 μL of the standard solution under the above operating
123 conditions, the internal standard, fendizoic acid and
124 cloperastine are eluted in this order, and each resolution
125 between these peaks is not less than 5, respectively.

126 System repeatability: When the test is repeated 6 times
127 with 20 μL of the standard solution under the above
128 operating conditions, the relative standard deviation of the
129 ratio of the peak area of cloperastine to that of the internal
130 standard is not more than 1.0%.

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

132 **Add the following to 9.41 Reagents,**

133 **Test Solutions:**

134 **Cloperastine fendizoate for assay**

135 $C_{20}H_{24}ClNO.C_{20}H_{14}O_4$ [Same as the monograph Clop-
136 erastine Fendizoate]

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