Cloperastine Fendizoate Tablets

クロペラスチンフェンジゾ酸塩錠

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

Method of preparation Prepare as directed under Tablets, with Cloperastine Fendizoate.

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

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 Cloperastine Fendizoate Tablets add exactly $V/10$ mL of the internal standard solution, add the mobile phase, shake vigorously until the tablet is disintegrated, add the mobile phase to make V mL so that each mL contains about 88 μg of cloperastine fendizoate ($C_{20}H_{24}ClNO.C_{20}H_{14}O_4$), and filter through a membrane filter with a pore size not exceeding 0.45 μm. Discard the first 10 mL of the filtrate, and use the subsequent filtrate as the sample solution. Then, proceed as directed in the Assay.

Amount (mg) of cloperastine fendizoate ($C_{20}H_{24}ClNO.C_{20}H_{14}O_4$)

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

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

Internal standard solution—A solution of ethyl parahydroxybenzoate in the mobile phase (3 in 2000).

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

Start the test with 1 tablet of Cloperastine Fendizoate Tablets, withdraw not less than 20 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 the first 10 mL of the filtrate, pipet V mL of the subsequent filtrate, add 1st fluid for dissolution test to make exactly V' mL so that each mL contains about 4.9 μg of cloperastine fendizoate ($C_{20}H_{24}ClNO.C_{20}H_{14}O_4$), and use this solution as the sample solution. Separately, weigh accurately about 25 mg of cloperastine fendizoate for assay, previously dried at 105ºC for 3 hours, and dissolve in methanol to make exactly 200 mL. Pipet 4 mL of this solution, add 1st fluid for dissolution test to make exactly 100 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*>, and determine the peak areas, A_T and A_S, of cloperastine in each solution.

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

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

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

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

Operating conditions—

Proceed as directed in the operating conditions in the Assay.

System suitability—

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

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

Assay Weigh accurately the mass of not less than 20 tablets of Cloperastine Fendizoate Tablets, and powder. Weigh accurately a portion of the powder, equivalent to about 4.4 mg of cloperastine fendizoate ($C_{20}H_{24}ClNO.C_{20}H_{14}O_4$), add exactly 5 mL of the internal standard solution, add 20 mL of the mobile phase, shake vigorously for 10 minutes, then add the mobile phase to make 50 mL, and filter through a membrane filter with a pore size not exceeding 0.45 μm. Discard the first 10 mL of the filtrate and use the subsequent filtrate as the sample solution. Separately, weigh accurately about 22 mg of cloperastine fendizoate for assay, previously dried at 105ºC for 3 hours, and dissolve in the mobile phase to make exactly 50 mL. Pipet 10 mL of this solution, add exactly 5 mL of the internal standard solution, add the mobile phase to make 50 mL, and use this solution as the standard solution. Perform the test with exactly 20 μL each of the sample solution

and standard solution as directed under Liquid Chromatography <2.01>, and calculate the ratios, Q_T and Q_S, of the peak area of cloperastine to that of the internal standard.

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

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

Internal standard solution — A solution of ethyl parahydroxybenzoate in the mobile phase (3 in 2000).

Operating conditions —

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

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

Column temperature: A constant temperature of about 25ºC.

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

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

System suitability —

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

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

Containers and storage Containers — Tight containers.

Add the following to 9.41 Reagents, Test Solutions:

Cloperastine fendizoate for assay $C_{20}H_{24}ClNO.C_{20}H_{14}O_4$ [Same as the monograph Cloperastine Fendizoate]