Mequitazine Fine Granules

Dissolution a <*6.10*> Conduct this procedure without exposure to light. Weigh accurately an amount of Mequitazine Fine Granules, equivalent to about 3 mg of mequitazine ($C_{20}H_{22}N_2S$) according to the labeled amount, and perform the test at 50 revolutions per minute according to the Paddle method, using 900 mL of 2nd fluid for dissolution test as the dissolution medium. Start the test, 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, and use the subsequent filtrate as the sample solution. Separately, weigh accurately about 15 mg of Mequitazine RS, previously dried under reduced pressure at 60ºC for 3 hours using phosphorus (V) oxide as a desiccant, dissolve in 50 mL of methanol, and add 2nd fluid for dissolution test to make exactly 100 mL. Pipet 5 mL of this solution, add 2nd fluid for dissolution test to make exactly 200 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*> according to the following conditions, and determine the peak areas, A_T and A_S, of mequitazine of both solutions.

The requirements are met if Mequitazine Fine Granules conform to the dissolution requirements.

Dissolution rate (%) with respect to the labeled amount of mequitazine ($C_{20}H_{22}N_2S$)
$= M_S/M_T \times A_T/A_S \times 1/C \times 45/2$

M_S: Amount (mg) of Mequitazine RS
M_T: Amount (g) of sample
C: Labeled amount (mg) of mequitazine ($C_{20}H_{22}N_2S$) in 1 g

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 254 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 35ºC.

Mobile phase: A mixture of trifluoroacetic acid TS and acetonitrile (3:2).

Flow rate: Adjust the flow rate so that the retention time of mequitazine is about 9 minutes.

System suitability—

System performance: When the procedure is run with 20 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of mequitazine are not less than 4000 and not more than 2.0, 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 peak area of mequitazine is not more than 2.0%.

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
6 mg/g	45 minutes	Not less than 75%

Dissolution b *<6.10>* Conduct this procedure without exposure to light. Weigh accurately an amount of Mequitazine Fine Granules, equivalent to about 3 mg of mequitazine ($C_{20}H_{22}N_2S$) according to the labeled amount, and perform the test at 50 revolutions per minute according to the Paddle method, using 900 mL of 2nd fluid for dissolution test as the dissolution medium. Start the test, 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 10mL of the filtrate, and use the subsequent filtrate as the sample solution. Separately, weigh accurately about 15 mg of Mequitazine RS, previously dried under reduced pressure at 60ºC for 3 hours using phosphorus (V) oxide as a desiccant, dissolve in 50 mL of methanol, and add 2nd solution for dissolution test to make exactly 100 mL. Pipet 5 mL of this solution, add 2nd fluid for dissolution test to make exactly 200 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>* according to the following conditions, and determine the peak areas, A_T and A_S, of mequitazine of both solutions.

The requirements are met if Mequitazine Fine Granules conform to the dissolution requirements.

Dissolution rate (%) with respect to the labeled amount of mequitazine ($C_{20}H_{22}N_2S$)

$= M_S/M_T \times A_T/A_S \times 1/C \times 45/2$

M_S: Amount (mg) of Mequitazine RS

M_T: Amount (g) of sample

C: Labeled amount (mg) of mequitazine ($C_{20}H_{22}N_2S$) in 1 g

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 254 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).

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Flow rate: Adjust the flow rate so that the retention time of mequitazine is about 9 minutes.

System suitability−

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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 peak area of mequitazine is not more than 2.0%.

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
6 mg/g	15 minutes	Not less than 85%