Dimemorfan Phosphate Tablets

Dissolution *<6.10>* Perform the test with 1 tablet of Dimemorfan Phosphate Tablets at 50 revolutions per minute according to the Paddle method, using 900 mL of water as the dissolution medium. 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 water to make exactly V' mL so that each mL contains about 11 μg of dimemorfan phosphate ($C_{18}H_{25}N.H_3PO_4$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 22 mg of Dimemorfan Phosphate RS, previously dried at 105ºC for 3 hours, and dissolve in water to make exactly 100 mL. Pipet 5 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 dimemorfan in each solution.

The requirements are met if Dimemorfan Phosphate Tablets conform to the dissolution requirements.

Dissolution rate (%) with respect to the labeled amount of dimemorfan phosphate ($C_{18}H_{25}N.H_3PO_4$)
$= M_S \times A_T/A_S \times V'/V \times 1/C \times 45$

M_S: Amount (mg) of Dimemorfan Phosphate RS

C: Labeled amount (mg) of dimemorfan phosphate ($C_{18}H_{25}N.H_3PO_4$) in 1 tablet

Operating conditions —

Detector: An ultraviolet absorption photometer (wavelength: 268 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 30ºC.

Mobile phase: To 10 mL of triethylamine add 950 mL of water, adjust to pH 2.5 with phosphoric acid, and add water to make 1000 mL. To 700 mL of this solution add 300 mL of acetonitrile.

Flow rate: Adjust the flow rate so that the retention time of dimemorfan is about 6 minutes.

System suitability —

System performance: When the procedure is run with 100 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of dimemorfan are not less than 3000 and not more than 2.0, respectively.

System repeatability: When the test is repeated 6 times with 100 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of dimemorfan is not more than 2.0%.

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
10mg	60 minutes	Not less than 75%

Dimemorfan Phosphate RS Dimemorfan Phosphate (JP). When dried, it contains not less than 99.0% of dimemorfan phosphate ($C_{18}H_{25}N.H_3PO_4$).