

Dimemorfan Phosphate Powder

Dissolution <6.10> Perform the test with an accurately weighed quantity of Dimemorfan Phosphate Powder, equivalent to about 10 mg of dimemorfan phosphate ($C_{18}H_{25}N.H_3PO_4$) according to the labeled amount, at 75 revolutions per minute according to the Paddle method, using 900 mL of 2nd fluid for dissolution test 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, and use the subsequent filtrate as the sample solution. Separately, weigh accurately about 22 mg of Dimemorfan Phosphate RS, previously dried at 105°C for 3 hours, and dissolve in 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 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 Powder conforms to the dissolution requirements.

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

M_S : Amount (mg) of Dimemorfan Phosphate RS

M_T : Amount (g) of sample

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

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 30°C.

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
100 mg/g	15 minutes	Not less than 75%

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