

Tocopherol Nicotinate Fine Granules

Dissolution <6.10> Weigh accurately an amount of Tocopherol Nicotinate Fine Granules, equivalent to about 0.2 mg of tocopherol nicotinate ($C_{35}H_{53}NO_3$) according to the labeled amount, and perform the test at 100 revolutions per minute according to the Paddle method, using 900 mL of a solution of sodium lauryl sulfate in disodium hydrogenphosphate-citric acid buffer solution, pH 6.8 (1 in 500) 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 22 mg of Tocopherol Nicotinate RS, dissolve in 5 mL of ethanol (99.5), add a solution of sodium lauryl sulfate in disodium hydrogen phosphate-citric acid buffer solution, pH 6.8 (1 in 500) 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> according to the following conditions, and determine the peak areas, A_T and A_S , of tocopherol nicotinate of both solutions.

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

$$\begin{aligned} &\text{Dissolution rate (\%)} \text{ with respect to the labeled amount of tocopherol nicotinate } (C_{35}H_{53}NO_3) \\ &= M_S / M_T \times A_T / A_S \times 1 / C \times 900 \end{aligned}$$

M_S : Amount (mg) of Tocopherol Nicotinate RS

M_T : Amount (g) of sample

C : Labeled amount (mg) of tocopherol nicotinate ($C_{35}H_{53}NO_3$) in 1 g

Operating conditions–

Detector: An ultraviolet absorption photometer (wavelength: 264 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 40°C.

Mobile phase: Methanol

Flow rate: Adjust the flow rate so that the retention time of tocopherol nicotinate is about 7 minutes.

System suitability–

System performance: When the procedure is run with 10 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of

tocopherol nicotinate are not less than 2500 and not more than 1.5, respectively.

System repeatability: When the test is repeated 6 times with 10 μ L of the standard solution under the above operating conditions, the relative standard deviation of the peak area of tocopherol nicotinate is not more than 1.5%.

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
400 mg/g	15 minutes	Not less than 80%

Disodium hydrogen phosphate-citric acid buffer solution, pH 6.8 To 1000 mL of 0.05 mol/L disodium hydrogen phosphate TS add a solution, prepared by dissolving 5.25 g of citric acid monohydrate in water to make 1000 mL, and adjust the pH to 6.8.