

Ascorbic Acid 200 mg/g and Calcium Pantothenate 3 mg/g Granules

Dissolution <6.10> Weigh accurately about 1 g of Ascorbic Acid 200 mg/g and Calcium Pantothenate 3 mg/g Granules, and perform the test 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, and use the subsequent filtrate as the sample solution (1). Pipet 5 mL of the sample solution (1), add 1st fluid for dissolution test to make exactly 100 mL, and use this solution as the sample solution (2).

The requirements are met if Ascorbic Acid 200 mg/g and Calcium Pantothenate 3 mg/g Granules conform to the dissolution requirements.

Ascorbic Acid

The procedures to the detection of absorption should be performed within 1 hour after collecting the dissolution medium.

Separately, weigh accurately about 22 mg of Ascorbic Acid RS, previously dried with desiccator (silica gel) for 24 hours, and dissolve in water to make exactly 100 mL. Pipet 5 mL of this solution, add 1st fluid for dissolution test to make exactly 100 mL, and use this solution as the standard solution. Determine the absorbances, A_T and A_S , of the sample solution (2) and standard solution at 243 nm as directed under Ultraviolet-visible Spectrophotometry <2.24>, using 1st fluid for dissolution test as the blank.

$$\begin{aligned} & \text{Dissolution rate (\%)} \text{ with respect to the labeled amount of ascorbic acid (C}_6\text{H}_8\text{O}_6\text{)} \\ & = M_S/M_T \times A_T/A_S \times 1/C \times 900 \end{aligned}$$

M_S : Amount (mg) of Ascorbic Acid RS

M_T : Amount (g) of sample

C: Labeled amount (mg) of ascorbic acid (C₆H₈O₆) in 1 tablet

Calcium Pantothenate

Separately, weigh accurately about 16.5 mg of Calcium Pantothenate RS, previously dried at 105°C for 4 hours, and dissolve in water to make exactly 100mL. Pipet 2 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 (1) 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 pantothenic acid.

Dissolution rate (%) with respect to the labeled amount of calcium pantothenate ($C_{18}H_{32}CaN_2O_{10}$)
 $= M_S/M_T \times A_T/A_S \times 1/C \times 18$

M_S : Amount (mg) of Calcium Pantothenate RS

M_T : Amount (g) of sample

C : Labeled amount (mg) of calcium pantothenate ($C_{18}H_{32}CaN_2O_{10}$) in 1 tablet

Operating conditions —

Detector: An ultraviolet absorption photometer (wavelength: 210 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 μ m in particle diameter).

Column temperature: A constant temperature of about 35°C.

Mobile phase: To 970 mL of 0.05 mol/L sodium dihydrogen phosphate TS, pH 2.6, add 30 mL of acetonitrile.

Flow rate: Adjust the flow rate so that the retention time of pantothenic acid is about 10 minutes.

System suitability —

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

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

Dissolution Requirements

| | Labeled amount | Specified minute | Dissolution rate |
|----------------------|----------------|------------------|-------------------|
| Ascorbic Acid | 200 mg/g | 15 minutes | Not less than 85% |
| Calcium Pantothenate | 3 mg/g | | Not less than 85% |

Ascorbic Acid RS Ascorbic Acid (JP).

Calcium Pantothenate RS Calcium Pantothenate (JP). When dried, it contains not less than 5.83 to 5.94% of nitrogen (N:14.01).