Aceglatone Tablets

Dissolution *<6.10>* Perform the test with 1 tablet of Aceglatone Tablets at 100 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 8 mL of the subsequent filtrate, add 1 mL of sodium hydroxide TS, shake for 20 minutes, and exposure for 5 minutes to ultrasonic vibration. To this solution add 1 drop of phenolphthalein TS, neutralize with dilute sulfuric acid, add water to make exactly 20 mL, and use this solution as the sample solution. Separately, weigh accurately about 16 mg of Aceglatone RS (previously determine the water *<2.48>* with 2 g by direct titration in volumetric titration), add 100 mL of water, and then add 10 mL of sodium hydroxide TS, shake for 20 minutes, and exposure for 5 minutes to ultrasonic vibration. To this solution add 1 drop of phenolphthalein TS, neutralize with dilute sulfuric acid, add water to make exactly 200 mL, and use this solution as the standard solution. Perform the test with exactly 50 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 acetic acid prepared by decomposing aceglatone in each solution by alkaline treatment.

The requirements are met if Aceglatone Tablets conform to the dissolution requirements.

Dissolution rate (%) with respect to the labeled amount of aceglatone ($C_{10}H_{10}O_8$)

$= M_S \times A_T/A_S \times 1/C \times 1125$

M_S: Amount (mg) of Aceglatone RS, calculated on the anhydrous basis

C: Labeled amount (mg) of aceglatone ($C_{10}H_{10}O_8$) in 1 tablet

Operating conditions —

Detector: An ultraviolet absorption photometer (wavelength: 210 nm).

Column: A stainless steel column 8 mm in inside diameter and 30 cm in length, packed with styrene-divinylbenzene copolymer cation exchange resin having a hydrogen ion-type 8% degree of crosslinking (9 μm in particle diameter).

Column temperature: A constant temperature of about 40ºC.

Mobile phase: Adjust the pH of water to 2.6 with phosphoric acid.

Flow rate: Adjust the flow rate so that the retention time of acetic acid is about 12 minutes.

System suitability —

System performance: When the procedure is run with 50 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of acetic

acid are not less than 10,000 and not more than 2.0, respectively.

System repeatability: When the test is repeated 6 times with 50 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of acetic acid is not more than 1.5%.

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
187.5 mg	120 minutes	Not less than 75%

Aceglatone RS Same as the monograph Aceglatone of the Japanese Pharamaceutical Codex. When dried, it contains not less than 99.0% of aceglatone ($C_{10}H_{10}O_8$).