Actarit Tablets

Dissolution <6.10> Perform the test with 1 tablet of Actarit 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 actarit ($C_{10}H_{11}NO_3$) according to the labeled amount, and use this solution as the sample solution. Separately, weigh accurately about 22 mg of Actarit RS, previously dried at 105ºC for 2 hours, and dissolve in water to make exactly 200 mL. Pipet 2 mL of this solution, add water to make exactly 20 mL, and use this solution as the standard solution. Perform the test with the sample solution and standard solution as directed under Ultraviolet-visible Spectrophotometry <2.24>, and determine the absorbances, A_T and A_S, at 244 nm.

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

Dissolution rate (%) with respect to the labeled amount of actarit ($C_{10}H_{11}NO_3$)

$= M_S \times A_T/A_S \times V'/V \times 1/C \times 45$

M_S: Amount (mg) of Actarit RS

C: Labeled amount (mg) of actarit ($C_{10}H_{11}NO_3$) in 1 tablet

Dissolution Requirements

Labeled amount	Specified minute	Dissolution rate
100 mg	30 minutes	Not less than 80%

Actarit RS $C_{10}H_{11}NO_3$: 193.20 4-acetylaminophenyl acetate. It meets the following requirements. Purify by the following method if needed.

Purification method—Dissolve, with heating 10 g of actarit in 30 mL of a mixture of acetone and water (1:1), and filter the insoluble substances. After cooling the filtrate to the room temperature, allow to stand overnight, and form white crystals. Dry the crystals so obtained at 50 to 60ºC for 8 hours.

Description—Actarit RS occurs as while crystals or crystalline powder.

Identification—Determine the infrared absorption spectrum of Actarit RS, previously dried, as directed in the potassium bromide disk method under Infrared Spectrophotometry <2.25>: it exhibits absorption at the wave numbers of about 3330 cm^{-1}, 1695 cm^{-1}, 1641 cm^{-1}, 1601 cm^{-1}, 1284 cm^{-1}, 1262 cm^{-1} and 738 cm^{-1}.

Purity Related substances—Dissolve 0.10 g of Actarit RS in 10 mL of acetone, and use this solution as the sample solution. To exactly 1 mL of this solution add acetone to make exactly 25 mL. Pipet 2 mL of this solution, add acetone to make exactly 20 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under Thin-layer Chromatography *<2.03>*. Spot 10 μL each of the sample solution and standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of tetrahydrofuran, hexane, acetic acid (100) and water (20:10:2:1) to a distance of about 10 cm, and air-dry the plate. Examine the plate under ultraviolet light (main wavelength: 254 nm): the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

Loss on drying <2.41>: not more than 0.5% (1 g, 105ºC, 2 hours).

Content: not less than 99.0 %. Assay—Weigh accurately about 0.3 g of Actarit RS, previously dried, dissolve in 30 mL of ethanol (95), and titrate *<2.50>* with 0.1 mol/L sodium hydroxide VS (potentiometric titration). Perform a blank determination in the same manner, and make any necessary correction.

Each mL of 0.1 mol/L sodium hydroxide VS
= 19.32 mg of $C_{10}H_{11}NO_3$