Roxithromycin Tablets

ロキシスロマイシン錠

Roxithromycin Tablets contain not less than 95.0% and not more than 110.0% of the labeled amount of roxithromycin ($C_{41}H_{76}N_2O_{15}$: 837.05).

Method of preparation Prepare as directed under Tablets, with Roxithromycin.

Identification To a quantity of powdered Roxithromycin Tablets, equivalent to 0.3 g (potency) of Roxithromycin, add 10 mL of acetonitrile, shake, and centrifuge. Evaporate the supernatant liquid on a water bath under reduced pressure, dry the residue at 60℃ for 1 hour under reduced pressure, and determine the infrared absorption spectrum of the residue as directed in the potassium bromide disk method under Infrared Spectrophotometry <*2.25*>: it exhibits absorption at the wave numbers of about 3460 cm^{-1}, 2940 cm^{-1}, 1728cm^{-1}, 1633cm^{-1} and 1464 cm^{-1}.

Uniformity of dosage unit <*6.02*> Perform either the Mass variation test, or the Content uniformity test according to the following method: it meets the requirement of the test.

To 1 tablet of Roxithromycin Tablets add 7*V*/10 mL of the mobile phase, disintegrate the tablet with ultrasonic waves, shake, add exactly *V*/25 mL of the internal standard solution, and add the mobile phase to make *V* mL so that each mL contains about 1.5 mg (potency) of roxithromycin ($C_{41}H_{76}N_2O_{15}$). Filter this solution through a membrane filter with a pore size not exceeding 0.45 μm, discard the first 5 mL of the filtrate, and use the subsequent filtrate as the sample solution. Then, proceed as directed in the Assay.

Amount [mg (potency)] of roxithromycin ($C_{41}H_{76}N_2O_{15}$)
$= M_S \times Q_T / Q_S \times V / 25$

M_S: Amount [mg (potency)] of Roxithromycin RS taken

Internal standard solution —A solution of isopropyl parahydroxybenzoate in the mobile phase (1 in 800).

Dissolution <*6.10*> When the test is performed at 50 revolutions per minute according to the Paddle method, using 900 mL of 2nd fluid for dissolution test as the dissolution medium, the dissolution rate in 30 minutes of Roxithromycin Tablets is not less than 80%.

Start the test with 1 tablet of Roxithromycin Tablets, 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 the dissolution medium to make exactly *V'* mL so that each mL contains about 0.17 mg (potency) of roxithromycin ($C_{41}H_{76}N_2O_{15}$), and use this solution as the sample solution. Separately, weigh accurately about 33 mg (potency) of Roxithromycin RS, dissolve in the dissolution medium 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 roxithromycin in each solution.

Dissolution rate (%) with respect to the labeled amount [mg (potency)] of roxithromycin ($C_{41}H_{76}N_2O_{15}$)
$= M_S \times A_T / A_S \times V' / V \times 1 / C \times 450$

M_S: Amount [mg (potency)] of Roxithromycin RS taken
C: Labeled amount [mg (potency)] of roxithromycin ($C_{41}H_{76}N_2O_{15}$) in 1 tablet

Operating conditions —

Detector: An ultraviolet absorption photometer (wavelength: 230 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 25℃.

Mobile phase: Dissolve 49.1 g of ammonium dihydrogen phosphate in 1000 mL of water, and adjust to pH 5.3 with 2 mol/L sodium hydroxide TS. To 690 mL of this solution add 310 mL of acetonitrile.

Flow rate: Adjust so that the retention time of roxithromycin is about 5 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 roxithromycin are not less than 2300 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 roxithromycin is not more than 1.0%.

Assay Weigh accurately the mass of not less than 20 Roxithromycin Tablets, and powder. Weigh accurately a portion of the powder, equivalent to about 38 mg (potency) of roxithromycin ($C_{41}H_{76}N_2O_{15}$), dissolve in the mobile phase, add exactly 1 mL of the internal standard solution, and then add the mobile phase to make 25 mL. Filter the solution through a membrane filter with a pore size not exceeding 0.45 μm, discard the first 5 mL of the filtrate, and use the subsequent filtrate as the sample solution. Separately, weigh accurately about 38 mg (potency) of Roxithromycin RS, dissolve in the

mobile phase, add exactly 1 mL of the internal standard solution, then add the mobile phase to make 25 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 calculate the ratios, Q_T and Q_S, of the peak area of roxithromycin to that of the internal standard.

Amount [mg (potency)] of roxithromycin ($C_{41}H_{76}N_2O_{15}$)
$= M_S \times Q_T / Q_S$

M_S: Amount [mg (potency)] of Roxithromycin RS taken

Internal standard solution —A solution of isopropyl parahydroxybenzoate in the mobile phase (1 in 800).

Operating conditions —

Detector: An ultraviolet absorption photometer (wavelength: 230 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 25 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 25℃.

Mobile phase: Dissolve 49.1 g of ammonium dihydrogen phosphate in 1000 mL of water, and adjust to pH 5.3 with 2 mol/L sodium hydroxide TS. To 690 mL of this solution add 310 mL of acetonitrile.

Flow rate: Adjust so that the retention time of roxithromycin is about 12 minutes.

System suitability —

System performance: When the procedure is run with 10 μL of the standard solution under the above operating conditions, roxithromycin and the internal standard are eluted in this order with the resolution between these peaks being not less than 10.

System repeatability: When the test is repeated 6 times with 10 μL of the standard solution under the above operating conditions, the relative standard deviation of the ratio of the peak area of roxithromycin to that of the internal standard is not more than 1.0%.

Containers and storage Containers—Tight containers.