Tandospirone Citrate Tablets

タンドスピロンクエン酸塩錠

Tandospirone Citrate Tablets contain not less than 95.0% and not more than 105.0% of the labeled amount of tandospirone citrate ($C_{21}H_{29}N_5O_2.C_6H_8O_7$: 575.61).

Method of preparation Prepare as directed under Tablets, with Tandospirone Citrate.

Identification To a quantity of powdered Tandospirone Citrate Tablets, equivalent to 15 mg of Tandospirone Citrate, add 70 mL of a mixture of water and methanol (1:1), shake for 30 minutes, add a mixture of water and methanol (1:1) to make 100 mL, and centrifuge. To 5 mL of the supernatant liquid add a mixture of water and methanol (1:1) to make 50 mL. Determine the absorption spectrum of this solution as directed under Ultraviolet-visible Spectrophotometry *<2.24>*: it exhibits a maximum between 236 nm and 240 nm.

Uniformity of dosage units *<6.02>* Perform the test according to the following method: it meets the requirement of the Content uniformity test.

To 1 tablet of Tandospirone Citrate Tablets add 60 mL of a mixture of water and methanol (1:1), shake until the tablet is completely disintegrated, and add a mixture of water and methanol (1:1) to make exactly 100 mL. Centrifuge this solution, pipet 15 mL of the supernatant liquid, add a mixture of water and methanol (1:1) to make exactly V mL so that each mL contains about 15 μg of tandospirone citrate ($C_{21}H_{29}N_5O_2.C_6H_8O_7$), and use this solution as the sample solution. Separately, weigh accurately about 15 mg of Tandospirone Citrate RS, previously dried in vacuum at 105℃ for 3 hours, and dissolve in a mixture of water and methanol (1:1) to make exactly 100 mL. Pipet 5 mL of this solution, add a mixture of water and methanol (1:1) to make exactly 50 mL, and use this solution as the standard solution. Determine the absorbances, A_T and A_S, of the sample solution and standard solution at 238 nm as directed under Ultraviolet-visible Spectrophotometry *<2.24>*.

Amount (mg) of tandospirone citrate ($C_{21}H_{29}N_5O_2.C_6H_8O_7$)
$= M_S \times A_T / A_S \times V / 150$

M_S: Amount (mg) of Tandospirone Citrate RS taken

Dissolution *<6.10>* When the test is performed at 50 revolutions per minute according to the Paddle method, using 900 mL of water as the dissolution medium, the dissolution rate in 15 minutes of Tandospirone Citrate Tablets is not less than 85%.

Start the test with 1 tablet of Tandospirone Citrate 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 not less than 10 mL of the first filtrate, pipet V mL of the subsequent filtrate, add water to make exactly V' mL so that each mL contains about 5.6 μg of tandospirone citrate ($C_{21}H_{29}N_5O_2.C_6H_8O_7$), and use this solution as the sample solution. Separately, weigh accurately about 22 mg of Tandospirone Citrate RS, previously dried in vacuum at 105℃ for 3 hours, and dissolve in water to make exactly 100 mL. Pipet 5 mL of this solution, 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 operating conditions described below, and determine the peak areas, A_T and A_S, of tandospirone in each solution.

Dissolution rate (%) with respect to the labeled amount of tandospirone citrate ($C_{21}H_{29}N_5O_2.C_6H_8O_7$)
$= M_S \times A_T / A_S \times V'/V \times 1/C \times 45/2$

M_S: Amount (mg) of Tandospirone Citrate RS taken
C: Labeled amount (mg) of tandospirone citrate ($C_{21}H_{29}N_5O_2.C_6H_8O_7$) in 1 tablet

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 239 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℃.

Mobile phase: Adjust the pH of a solution of sodium 1-heptanesulfonate (1 in 1000) to 3.0 with phosphoric acid. To 700 mL of this solution add 300 mL of acetonitrile for liquid chromatography.

Flow rate: Adjust so that the retention time of tandospirone is about 6 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 tandospirone are not less than 3000 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 tandospirone is not more than 2.0%.

Assay Weigh accurately the mass of not less than 20 tablets of Tandospirone Citrate Tablets, and powder. Weigh accurately a portion of the powder, equivalent to about 25 mg of tandospirone citrate ($C_{21}H_{29}N_5O_2.C_6H_8O_7$), add 30 mL of the

mobile phase, shake for 15 minutes, and add the mobile phase to make exactly 50 mL, and centrifuge, Pipet 15 mL of the supernatant liquid, add the mobile phase to make exactly 25 mL, and use this solution as the sample solution. Separately, weigh accurately about 50 mg of Tandospirone Citrate RS, previously dried in vacuum at 105℃ for 3 hours, and dissolve in the mobile phase to make exactly 50 mL. Pipet 15 mL of this solution, add the mobile phase to make exactly 50 mL, and use this solution as the standard solution. Perform the test with exactly 5 μL each of the sample solution and standard solution as directed under Liquid Chromatography *<2.01>* according to the operating conditions described below, and determine the peak areas, A_T and A_S, of tandospirone in each solution.

Amount (mg) of tandospirone citrate ($C_{21}H_{29}N_5O_2.C_6H_8O_7$)
$= M_S \times A_T / A_S \times 1/2$

M_S: Amount (mg) of Tandospirone Citrate RS taken

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 239 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 30℃.

Mobile phase: Dissolve 1.36 g of potassium dihydrogen phosphate in water to make 1000 mL, and adjust to pH 7.0 with a solution of sodium hydroxide (1 in 10). To 400 mL of this solution add 600 mL of acetonitrile for liquid chromatography.

Flow rate: 1.0 mL per minute.

System suitability—

System performance: When the procedure is run with 5 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of tandospirone are not less than 5000 and not more than 1.5, respectively.

System repeatability: When the test is repeated 6 times with 5 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of tandospirone is not more than 1.0%.

Containers and storage Containers—Tight containers.

Add the following to 9.01 Reference Standards (1):

Tandospirone Citrate RS