Rilmazafone Hydrochloride Tablets

リルマザホン塩酸塩錠

Rilmazafone Hydrochloride Tablets contain not less than 93.0% and not more than 107.0% of the labeled amount of rilmazafone hydrochloride hydrate ($C_{21}H_{20}Cl_2N_6O_3.HCl.2H_2O$: 547.82).

Method of preparation Prepare as directed under Tablets, with Rilmazafone Hydrochloride Hydrate.

Identification To a quantity of powdered Rilmazafone Hydrochloride Tablets, equivalent to 10 mg of Rilmazafone Hydrochloride Hydrate, add 5 mL of methanol, shake for 10 minutes, and centrifuge. Filter the supernatant liquid with a membrane filter with a pore size not exceeding 0.45 μm, and use the filtrate as the sample solution. Separately, dissolve 2 mg of rilmazafone hydrochloride hydrate in 1 mL of methanol, 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 ethyl acetate, acetonitrile, water and acetic acid (100) (8:4:3:3) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): the principal spot obtained from the sample solution and the spot from the standard solution show the same *R*f value.

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 Rilmazafone Hydrochloride Tablets add *V* mL of water so that each mL contains about 0.2 mg of rilmazafone hydrochloride hydrate ($C_{21}H_{20}Cl_2N_6O_3.HCl.2H_2O$). Add exactly 2*V* mL of the internal standard solution, shake vigorously for 10 minutes, and filter with 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 20 mg of Rilmazafone Hydrochloride RS (separately determine the water <*2.48*> in the same manner as Rilmazafone Hydrochloride Hydrate), and dissolve in water to make exactly 100 mL. Pipet 10 mL of this solution, add exactly 20 mL of the internal standard solution, and use this solution as the standard solution. Then, proceed as directed in the Assay under Rilmazafone Hydrochloride Hydrate.

Amount (mg) of rilmazafone hydrochloride hydrate ($C_{21}H_{20}Cl_2N_6O_3.HCl.2H_2O$)

$= M_S \times Q_T / Q_S \times V / 100 \times 1.070$

M_S: Amount (mg) of Rilmazafone Hydrochloride RS taken, calculated on the anhydrous basis

Internal standard solution—A solution of propyl parahydroxybenzoate in a mixture of water and acetonitrile (1:1) (3 in 100,000).

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 Rilmazafone Hydrochloride Tablets is not less than 85%.

Start the test with 1 tablet of Rilmazafone Hydrochloride 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 water to make exactly *V'* mL so that each mL contains about 1.1 μg of rilmazafone hydrochloride hydrate ($C_{21}H_{20}Cl_2N_6O_3.HCl.2H_2O$), and use this solution as the sample solution. Separately, weigh accurately about 22 mg of Rilmazafone Hydrochloride RS (separately determine the water <*2.48*> in the same manner as Rilmazafone Hydrochloride Hydrate), and dissolve in water to make exactly 100 mL. Pipet 5 mL of this solution, add water to make exactly 100 mL. Then, pipet 5 mL of this solution, add water to make exactly 50 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 rilmazafone in each solution.

Dissolution rate (%) with respect to the labeled amount of rilmazafone hydrochloride hydrate ($C_{21}H_{20}Cl_2N_6O_3.HCl.2H_2O$)

$= M_S \times A_T / A_S \times V' / V \times 1 / C \times 9 / 2 \times 1.070$

M_S: Amount (mg) of Rilmazafone Hydrochloride RS taken, calculated on the anhydrous basis

C: Labeled amount (mg) of rilmazafone hydrochloride hydrate ($C_{21}H_{20}Cl_2N_6O_3.HCl.2H_2O$) in 1 tablet

Operating conditions—

Proceed as directed in the operating conditions in the Assay under Rilmazafone Hydrochloride Hydrate.

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 rilmazafone are not less than 5000 and not more than 1.5, 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 rilmazafone is not more than 2.0%.

Assay Weigh accurately the mass of not less than 20 tablets of Rilmazafone Hydrochloride Tablets, and powder. Weigh accurately a portion of the powder, equivalent to about 2 mg of rilmazafone hydrochloride hydrate ($C_{21}H_{20}Cl_2N_6O_3.HCl.2H_2O$), add 10 mL of water and exactly 20 mL of the internal standard solution, shake vigorously for 10 minutes, and filter 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 20 mg of Rilmazafone Hydrochloride RS (separately determine the water <*2.48*> in the same manner as Rilmazafone Hydrochloride Hydrate), and dissolve in water to make exactly 100 mL. Pipet 10 mL of this solution, add exactly 20 mL of the internal standard, and use this solution as the standard solution. Then, proceed as directed in the Assay under Rilmazafone Hydrochloride Hydrate.

Amount (mg) of rilmazafone hydrochloride hydrate ($C_{21}H_{20}Cl_2N_6O_3.HCl.2H_2O$)

$$= M_S \times Q_T / Q_S \times 1/10 \times 1.070$$

M_S: Amount (mg) of Rilmazafone Hydrochloride RS taken, calculated on the anhydrous basis

Internal standard solution—A solution of propyl parahydroxybenzoate in a mixture of water and acetonitrile (1:1) (3 in 100,000).

Containers and storage Containers—Well-closed containers.

Add the following to 9.01 Reference Standards (1):

Rilmazafone hydrochloride RS

Add the following to 9.41 Reagents, Test Solutions:

Rilmazafone hydrochloride hydrate
$C_{21}H_{20}Cl_2N_6O_3.HCl.2H_2O$ [Same as the namesake monograph]