Perospirone Hydrochloride Tablets

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Perospirone Hydrochloride Tablets contain not less than 95.0% and not more than 105.0% of the labeled amount of perospirone hydrochloride ($C_{23}H_{30}N_4O_2S$.HCl: 463.04).

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

Identification **(1)** To a quantity of powdered Perospirone Hydrochloride Tablets, equivalent to 10 mg of Perospirone Hydrochloride Hydrate, add about 60 mL of 0.01 mol/L hydrochloric acid TS, shake, then add 0.01 mol/L hydrochloric acid TS to make 100 mL, and filter. To 10 mL of the filtrate add 0.01 mol/L hydrochloric acid TS to make 100 mL. Determine the absorption spectrum of the solution as directed under Ultraviolet-visible Spectrophotometry *<2.24>*: it exhibits maxima between 228 nm and 232 nm, and between 313 nm and 317 nm.

(2) To a quantity of powdered Perospirone Hydrochloride Tablets, equivalent to 4 mg of Perospirone Hydrochloride Hydrate, add 4 mL of methanol, shake for 5 minutes, then centrifuge, and use the supernatant liquid as the sample solution. Separately, dissolve 10 mg of Perospirone Hydrochloride RS in 10 mL of methanol, and use this solution as the standard solution. Perform the test with the sample solution and standard solution as directed under Thin-layer Chromatography *<2.03>*. Spot 20 μL each of the sample solution and standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Then develop the plate with a mixture of cyclohexane, isopropylamine and acetone (16:2:1) 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.

Purity Related substances—Being specified separately when the drug is granted approval based on the Law.

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

To 1 tablet of Perospirone Hydrochloride Tablets add *V*/2 mL of the mobile phase, shake for 15 minutes, and add the mobile phase to make exactly *V* mL so that each mL contains about 80 μg of perospirone hydrochloride ($C_{23}H_{30}N_4O_2S$.HCl). Centrifuge this solution, and use the supernatant liquid as the sample solution. Then, proceed as directed under the Assay.

Amount (mg) of perospirone hydrochloride ($C_{23}H_{30}N_4O_2S$.HCl)
$= M_S \times A_T / A_S \times V / 500$

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

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 Perospirone Hydrochloride Tablets is not less than 75%.

Start the test with 1 tablet of Perospirone Hydrochloride Tablets, withdraw not less than 10 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 5 mL of the first filtrate, pipet *V* mL of the subsequent filtrate, add the dissolution medium to make exactly *V'* mL so that each mL contains about 4.4 μg of perospirone hydrochloride ($C_{23}H_{30}N_4O_2S$.HCl), and use this solution as the sample solution. Separately, weigh accurately about 48 mg of Perospirone Hydrochloride RS (separately determine the water *<2.48>* in the same manner as Perospirone Hydrochloride Hydrate), and dissolve in methanol to make exactly 50 mL. Pipet 2 mL of this solution, add the dissolution medium to make exactly 100 mL. Pipet 5 mL of this solution, add dissolution medium to make exactly 20 mL, and use this solution as the standard solution. Perform the test with 10 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 perospirone in each solution.

Dissolution rate (%) with respect to the labeled amount of perospirone hydrochloride ($C_{23}H_{30}N_4O_2S$.HCl)
$= M_S \times A_T / A_S \times V' / V \times 1 / C \times 9$

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

C: Labeled amount (mg) of perospirone hydrochloride ($C_{23}H_{30}N_4O_2S$.HCl) in 1 tablet

Operating conditions—

Proceed as directed in the operating conditions in the Assay.

System suitability—

Proceed as directed in the system suitability in the Assay.

Assay Weigh accurately not less than 20 Perospirone Hydrochloride Tablets, and powder. Weigh accurately a quantity of the powder, equivalent to about 20 mg of perospirone hydrochloride ($C_{23}H_{30}N_4O_2S$.HCl), add exactly 50 mL of the mobile phase, shake for 15 minutes, and centrifuge. Pipet 10 mL of the supernatant liquid, add the mobile phase to make exactly 50 mL, and use this solution as the sample solution. Separately, weigh accurately about 43 mg of Perospirone Hydrochloride RS (separately determine the water *<2.48>* in the same manner as Perospirone Hydrochloride Hydrate), dissolve in the mobile phase to make exactly 50 mL. Pipet 5 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 10 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 perospirone in each solution.

Amount (mg) of perospirone hydrochloride ($C_{23}H_{30}N_4O_2S.HCl$)
$= M_S \times A_T / A_S \times 1/2$

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

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 315 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 7.5 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 25°C.

Mobile phase: Dissolve 1.0 g of sodium 1-heptane sulfonate in 950 mL of water, adjust to pH 2.5 with phosphoric acid, and add water to make 1000 mL. To 750 mL of this solution add 400 mL of acetonitrile and 100 mL of methanol.

Flow rate: Adjust so that the retention time of perospirone is about 5 minutes.

System suitability—

System performance: When the procedure is run with 10 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of perospirone are not less than 3000 and not more than 2.0, respectively.

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 peak area of perospirone is not more than 1.0%.

Containers and storage Containers—Tight containers.

Add the following to 9.01 Reference Standards (1):

Perospirone Hydrochloride RS