Irbesartan Tablets

イルベサルタン錠

Irbesartan Tablets contain not less than 95.0% and not more than 105.0% of the labeled amount of irbesartan ($C_{25}H_{28}N_6O$: 428.53).

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

Identification To a quantity of powdered Irbesartan Tablets, equivalent to about 25 mg of Irbesartan, add 2 mL of acetone, shake, and filter through a membrane filter with a pore size not exceeding 0.45 μm. Evaporate the filtrate to dryness under a current of nitrogen. Determine the infrared absorption spectrum of the residue as directed in the potassium bromide disk method under Infrared Spectrophotometry *<2.25>*: it exhibits absorptions at the wave numbers of about 1733 cm^{-1}, 1617 cm^{-1}, 1435 cm^{-1} and 758 cm^{-1}.

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

To 1 tablet of Irbesartan Tablets add 1.5 mL of water, shake thoroughly to disintegrate, and add 15 mL of methanol. Shake thoroughly for 15 minutes, add methanol to make exactly 20 mL, and centrifuge. Pipet *V* mL of the supernatant liquid, equivalent to about 20 mg of irbesartan ($C_{25}H_{28}N_6O$), and add a mixture of water and acetonitrile (3:2) to make exactly 20 mL. Pipet 2.5 mL of this solution, add a mixture of water and acetonitrile (3:2) to make exactly 20 mL, and use this solution as the sample solution. Then, proceed as directed in the Assay.

Amount (mg) of irbesartan ($C_{25}H_{28}N_6O$)
$= M_S \times A_T / A_S \times 16 / V$

M_S: Amount (mg) of irbesartan for assay 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 45 minutes of 50-mg and 100-mg tablets is not less than 85%, and that in 60 minutes of 200-mg tablet is not less than 70%.

Start the test with 1 tablet of Irbesartan 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 the first 3 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 22 μg of irbesartan ($C_{25}H_{28}N_6O$), and use this solution as the sample solution. Separately, weigh accurately about 44 mg of irbesartan for assay (separately determine the water *<2.48>* in the same manner as Irbesartan), and dissolve in methanol to make exactly 20 mL. Pipet 2 mL of this solution, add the dissolution medium to make exactly 200 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 244 nm as directed under Ultraviolet-visible Spectrophotometry *<2.24>*, using the dissolution medium as the control.

Dissolution rate (%) with respect to the labeled amount of irbesartan ($C_{25}H_{28}N_6O$)
$= M_S \times A_T / A_S \times V' / V \times 1 / C \times 45$

M_S: Amount (mg) of irbesartan for assay taken, calculated on the anhydrous basis
C: Labeled amount (mg) of irbesartan ($C_{25}H_{28}N_6O$) in 1 tablet

Assay To 10 Irbesartan Tablets add 15 mL of water, shake thoroughly to disintegrate, and add 150 mL of methanol. Shake thoroughly for 15 minutes, add methanol to make exactly 200 mL, and centrifuge. Pipet *V* mL of the supernatant liquid, equivalent to about 20 mg of irbesartan ($C_{25}H_{28}N_6O$), and add a mixture of water and acetonitrile (3:2) to make exactly 20 mL. Pipet 2.5 mL of this solution, add a mixture of water and acetonitrile (3:2) to make exactly 20 mL, and use this solution as the sample solution. Separately, weigh accurately about 25 mg of irbesartan for assay (separately determine the water *<2.48>* in the same manner as Irbesartan), dissolve in methanol to make exactly 10 mL. Pipet 2.5 mL of this solution, add a mixture of water and acetonitrile (3:2) to make exactly 50 mL, and use this solution as the standard solution. Perform the test with 15 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 irbesartan in each solution.

Amount (mg) of irbesartan ($C_{25}H_{28}N_6O$)
$= M_S \times A_T / A_S \times 16 / V$

M_S: Amount (mg) of irbesartan for assay taken, calculated on the anhydrous basis

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 220 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: To 5.5 mL of phosphoric acid add 950 mL of water, adjust to pH 3.0 with triethylamine, and add water to make 1000 mL. To 3 volume of this solution add 2 volume of acetonitrile.

Flow rate: Adjust so that the retention time of irbesartan is about 13 minutes.

System suitability—

System performance: When the procedure is run with 15 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of irbesartan are not less than 10,000 and not more than 1.5, respectively.

System repeatability: When the test is repeated 6 times with 15 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of irbesartan is not more than 1.0%.

Containers and storage Containers－Tight containers.

Add the following to 9.41 Reagents, Test Solutions:

Irbesartan for assay $C_{25}H_{28}N_6O$ [Same as the monograph Irbesartan.]