Pranlukast Capsules

プランルカストカプセル

Pranlukast Capsules contain not less than 95.0% and not more than 105.0% of the labeled amount of pranlukast hydrate ($C_{27}H_{23}N_5O_4.^1/_2H_2O$: 490.51).

Method of preparation Prepare as directed under Capsules, with Pranlukast Hydrate.

Identification Take out the contents of Pranlukast Capsules, to a quantity of the contents, equivalent to 10 mg of Pranlukast Hydrate, add 100 mL of ethanol (99.5), shake thoroughly, and centrifuge. To 1 mL of the supernatant liquid add ethanol (99.5) to make 10 mL. Determine the absorption spectrum of this solution as directed under Ultraviolet-visible Spectrophotometry *<2.24>*: it exhibits a maximum between 256 nm and 260 nm, and a shoulder between 310 nm and 318 nm.

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

Take out the contents of 1 capsule of Pranlukast Capsules, dissolve in 25 mL of dimethylsulfoxide, and add acetonitrile to make exactly 100 mL. Pipet V mL of this solution, add a mixture of acetonitrile and dimethylsulfoxide (3:1) to make exactly V' mL so that each mL contains about 0.45 mg of pranlukast hydrate ($C_{27}H_{23}N_5O_4.^1/_2H_2O$). Pipet 8 mL of this solution, add exactly 9 mL of the internal standard solution, then add 1 mL of a mixture of acetonitrile and dimethylsulfoxide (3:1), and use this solution as the sample solution. Then, proceed as directed in the Assay.

Amount (mg) of pranlukast hydrate ($C_{27}H_{23}N_5O_4.^1/_2H_2O$)
$= M_S \times Q_T / Q_S \times V' / V \times 9/4 \times 1.0187$

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

Internal standard solution—A solution of isoamyl parahydroxybenzoate in a mixture of acetonitrile and dimethylsulfoxide (3:1) (1 in 2500).

Dissolution *<6.10>* When the test is performed at 100 revolutions per minute according to the Paddle method, using 900 mL of a solution, prepared by dissolving 1 g of polysorbate 80 in 2nd fluid for dissolution test to make 200 mL, as the dissolution medium, the dissolution rate in 90 minutes of Pranlukast Capsules is not less than 80%.

Start the test with 1 capsule of Pranlukast Capsules, 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 the dissolution medium to make exactly V' mL so that each mL contains about 5 μg of pranlukast hydrate ($C_{27}H_{23}N_5O_4.^1/_2H_2O$), and use this solution as the sample solution. Separately, weigh accurately about 25 mg of Pranlukast RS (separately, determine the water *<2.48>* in the same manner as Pranlukast Hydrate), dissolve in 5 mL of dimethylsulfoxide, and add the dissolution medium to make exactly 100 mL. Pipet 2 mL of this solution, add the dissolution medium to make exactly 100 mL, and use this solution as the standard solution. Determine the absorbances, A_T and A_S, at 260 nm of the sample solution and standard solution as directed under Ultraviolet-visible Spectrophotometry *<2.24>*, using the dissolution medium as the blank.

Dissolution rate (%) with respect to the labeled amount of pranlukast hydrate ($C_{27}H_{23}N_5O_4.^1/_2H_2O$)
$= M_S \times A_T / A_S \times V' / V \times 1/C \times 18 \times 1.0187$

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

C : Labeled amount (mg) of pranlukast hydrate ($C_{27}H_{23}N_5O_4.^1/_2H_2O$) in 1 capsule

Assay Take out the contents of 10 Pranlukast Capsules, dissolve in 25 mL of dimethylsulfoxide, and add acetonitrile to make exactly 100 mL. Pipet V mL of the supernatant liquid, equivalent to about 45 mg of pranlukast hydrate ($C_{27}H_{23}N_5O_4.^1/_2H_2O$), and add a mixture of acetonitrile and dimethylsulfoxide (3:1) to make exactly 100 mL. Pipet 8 mL of this solution, add exactly 9 mL of the internal standard solution, then add 1 mL of a mixture of acetonitrile and dimethylsulfoxide (3:1), and use this solution as the sample solution. Separately, weigh accurately about 20 mg of Pranlukast RS (separately, determine the water *<2.48>* in the same manner as Pranlukast Hydrate), dissolve in a mixture of acetonitrile and dimethylsulfoxide (3:1) to make exactly 50 mL. Pipet 5 mL of this solution, add exactly 5 mL of the internal standard solution, and use this soluion as the standard solution. Then, proceed as directed in the Assay for Pranlukast Hydrate.

Amount (mg) of pranlukast hydrate ($C_{27}H_{23}N_5O_4.^1/_2H_2O$) in 1 capsule of Pranlukast Capsules
$= M_S \times Q_T / Q_S \times 1 / V \times 45/2 \times 1.0187$

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

Internal standard solution—A solution of isoamyl parahydroxybenzoate in a mixture of acetonitrile and dimethylsulfoxide (3:1) (1 in 2500).

Containers and storage Containers—Tight containers.