

1 Pralukast Capsules

2 プランルカストカプセル

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4 Pralukast Capsules contain not less than 95.0% and
5 not more than 105.0% of the labeled amount of
6 pralukast hydrate ($C_{27}H_{23}N_5O_4 \cdot \frac{1}{2}H_2O$; 490.51).

7 **Method of preparation** Prepare as directed under Cap-
8 sules, with Pralukast Hydrate.

9 **Identification** Take out the contents of Pralukast Cap-
10 sules, to a quantity of the contents, equivalent to 10 mg of
11 Pralukast Hydrate, add 100 mL of ethanol (99.5), shake
12 thoroughly, and centrifuge. To 1 mL of the supernatant liquid
13 add ethanol (99.5) to make 10 mL. Determine the absorption
14 spectrum of this solution as directed under Ultraviolet-visible
15 Spectrophotometry <2.24>: it exhibits a maximum between
16 256 nm and 260 nm, and a shoulder between 310 nm and 318
17 nm.

18 **Uniformity of dosage units** <6.02> Perform the Mass var-
19 iation test, or the Content uniformity test according to the fol-
20 lowing method: it meets the requirement.

21 Take out the contents of 1 capsule of Pralukast Capsules,
22 dissolve in 25 mL of dimethylsulfoxide, and add acetonitrile
23 to make exactly 100 mL. Pipet V mL of this solution, add a
24 mixture of acetonitrile and dimethylsulfoxide (3:1) to make
25 exactly V' mL so that each mL contains about 0.45 mg of
26 pralukast hydrate ($C_{27}H_{23}N_5O_4 \cdot \frac{1}{2}H_2O$). Pipet 8 mL of this
27 solution, add exactly 9 mL of the internal standard solution,
28 then add 1 mL of a mixture of acetonitrile and dimethyl-
29 sulfoxide (3:1), and use this solution as the sample solution.
30 Then, proceed as directed in the Assay.

31 Amount (mg) of pralukast hydrate ($C_{27}H_{23}N_5O_4 \cdot \frac{1}{2}H_2O$)

$$32 = M_S \times Q_T / Q_S \times V' / V \times 9 / 4 \times 1.0187$$

33 M_S : Amount (mg) of Pralukast RS taken, calculated on
34 the anhydrous basis

35 **Internal standard solution**—A solution of isoamyl parahy-
36 droxybenzoate in a mixture of acetonitrile and dimethyl-
37 sulfoxide (3:1) (1 in 2500).

38 **Dissolution** <6.10> When the test is performed at 100 rev-
39 olutions per minute according to the Paddle method, using
40 900 mL of a solution, prepared by dissolving 1 g of polysorb-
41 ate 80 in 2nd fluid for dissolution test to make 200 mL, as the
42 dissolution medium, the dissolution rate in 90 minutes of
43 Pralukast Capsules is not less than 80%.

44 Start the test with 1 capsule of Pralukast Capsules, with-
45 draw not less than 20 mL of the medium at the specified mi-
46 nute after starting the test, and filter through a membrane fil-
47 ter with a pore size not exceeding 0.45 μ m. Discard not less
48 than 10 mL of the first filtrate, pipet V mL of the subsequent

49 filtrate, add the dissolution medium to make exactly V' mL
50 so that each mL contains about 5 μ g of pralukast hydrate
51 ($C_{27}H_{23}N_5O_4 \cdot \frac{1}{2}H_2O$), and use this solution as the sample so-
52 lution. Separately, weigh accurately about 25 mg of
53 Pralukast RS (separately, determine the water <2.48> in the
54 same manner as Pralukast Hydrate), dissolve in 5 mL of di-
55 methylsulfoxide, and add the dissolution medium to make
56 exactly 100 mL. Pipet 2 mL of this solution, add the dissolu-
57 tion medium to make exactly 100 mL, and use this solution
58 as the standard solution. Determine the absorbances, A_T and
59 A_S , at 260 nm of the sample solution and standard solution as
60 directed under Ultraviolet-visible Spectrophotometry <2.24>,
61 using the dissolution medium as the blank.

62 Dissolution rate (%) with respect to the labeled amount of
63 pralukast hydrate ($C_{27}H_{23}N_5O_4 \cdot \frac{1}{2}H_2O$)

$$64 = M_S \times A_T / A_S \times V' / V \times 1 / C \times 18 \times 1.0187$$

65 M_S : Amount (mg) of Pralukast RS taken, calculated on
66 the anhydrous basis

67 C : Labeled amount (mg) of pralukast hydrate
68 ($C_{27}H_{23}N_5O_4 \cdot \frac{1}{2}H_2O$) in 1 capsule

69 **Assay** Take out the contents of 10 Pralukast Capsules,
70 dissolve in 25 mL of dimethylsulfoxide, and add acetonitrile
71 to make exactly 100 mL. Pipet V mL of the supernatant liq-
72 uid, equivalent to about 45 mg of pralukast hydrate
73 ($C_{27}H_{23}N_5O_4 \cdot \frac{1}{2}H_2O$), and add a mixture of acetonitrile and
74 dimethylsulfoxide (3:1) to make exactly 100 mL. Pipet 8 mL
75 of this solution, add exactly 9 mL of the internal standard so-
76 lution, then add 1 mL of a mixture of acetonitrile and dime-
77 thylsulfoxide (3:1), and use this solution as the sample solu-
78 tion. Separately, weigh accurately about 20 mg of Pralukast
79 RS (separately, determine the water <2.48> in the same man-
80 ner as Pralukast Hydrate), dissolve in a mixture of acetonit-
81 rile and dimethylsulfoxide (3:1) to make exactly 50 mL. Pi-
82 pet 5 mL of this solution, add exactly 5 mL of the internal
83 standard solution, and use this solution as the standard solu-
84 tion. Then, proceed as directed in the Assay for Pralukast
85 Hydrate.

86 Amount (mg) of pralukast hydrate ($C_{27}H_{23}N_5O_4 \cdot \frac{1}{2}H_2O$) in 1
87 capsule of Pralukast Capsules

$$88 = M_S \times Q_T / Q_S \times 1 / V \times 45 / 2 \times 1.0187$$

89 M_S : Amount (mg) of Pralukast RS taken, calculated on
90 the anhydrous basis

91 **Internal standard solution**—A solution of isoamyl parahy-
92 droxybenzoate in a mixture of acetonitrile and dimethyl-
93 sulfoxide (3:1) (1 in 2500).

94 **Containers and storage** Containers—Tight containers.