

1 **Lanconazole Cutaneous Solution**

2 ラノコナゾール外用液

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4 Lanconazole Cutaneous Solution is a liquid for
5 external use.

6 It contains not less than 95.0 w/v% and not more
7 than 105.0 w/v% of the labeled amount of
8 lanconazole ($C_{14}H_{10}ClN_3S_2$; 319.83).

9 **Method of preparation** Prepare as directed under Liq-
10 uids and Solutions for Cutaneous Application, with Lano-
11 conazole.

12 **Identification** To a volume of Lanconazole Cutaneous
13 Solution, equivalent to 50 mg of Lanconazole, add water
14 enough to produce precipitate, and shake vigorously. Filter
15 this solution, rinse the vessel with a suitable amount of wa-
16 ter, and collect the precipitates. Wash the precipitates with
17 100 mL of water, dissolve in acetone, and dry under re-
18 duced pressure. If there are water droplets in the residue,
19 dissolve the residue in 40 mL of acetone, and dry again un-
20 der reduced pressure. Dissolve the residue in 30 mL of ac-
21 etone, and use this solution as the sample solution. Sepa-
22 rately, dissolve 10 mg of lanconazole in 10 mL of acetone,
23 and use this solution as the standard solution. Perform the
24 test with these solutions as directed under Thin-layer Chro-
25 matography <2.03>. Spot 10 μ L each of the sample solution
26 and standard solution on a plate of silica gel with fluores-
27 cent indicator for thin-layer chromatography. Develop the
28 plate with a mixture of ethyl acetate, toluene, methanol and
29 ammonia solution (28) (400:400:20:1) to a distance of
30 about 15 cm, and air-dry the plate. Examine under ultravi-
31 olet light (main wavelength: 254 nm): the principal spots
32 obtained from the sample solution and the spot from the
33 standard solution show the same *R_f* value.

34 **Assay** Conduct this procedure using light-resistant ves-
35 sels. Pipet a volume of Lanconazole Cutaneous Solution,
36 equivalent to about 50 mg of lanconazole ($C_{14}H_{10}ClN_3S_2$),
37 and add methanol to make exactly 50 mL. Pipet 15 mL of
38 this solution, add exactly 10 mL of the internal standard
39 solution, add methanol to make 100 mL, and use this solu-
40 tion as the sample solution. Separately, weigh accurately
41 about 15 mg of Lanconazole RS, previously dried at
42 105°C for 2 hours, dissolve in methanol, and add exactly
43 10 mL of the internal standard solution. Add methanol to
44 make 100 mL, and use this solution as the standard solution.
45 Perform the test with 10 μ L each of the sample solution and
46 standard solution as directed under Liquid Chromatog-
47 raphy <2.01> according to the following conditions, and
48 calculate the ratios, Q_T and Q_S , of the peak area of lanocon-
49 azole to that of the internal standard.

50 Amount (mg) of lanconazole ($C_{14}H_{10}ClN_3S_2$)
51 $= M_S \times Q_T / Q_S \times 10 / 3$

52 M_S : Amount (mg) of Lanconazole RS taken

53 **Internal standard solution**—A solution of diisopropyl 1,3-
54 dithiolan-2-ylidenemalonate in methanol (1 in 1000).

55 **Operating conditions**—

56 Proceed as directed in the operating conditions in the
57 Assay under Lanconazole.

58 **System suitability**—

59 System performance: When the procedure is run with 10
60 μ L of the standard solution under the above operating
61 conditions, lanconazole and the internal standard are
62 eluted in this order with the resolution between these peaks
63 being not less than 3.

64 System repeatability: When the test is repeated 6 times
65 with 10 μ L of the standard solution under the above
66 operating conditions, the relative standard deviation of the
67 ratio of the peak area of lanconazole to that of the internal
68 standard is not more than 1.0%.

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

70 Storage—Light-resistant.

71 **Add the following to 9.01 Reference**
72 **Standards (1):**

73 **Lanconazole RS**

74 **Add the following to 9.41 Reagents,**
75 **Test Solutions:**

76 **Diisopropyl 1,3-dithiolan-2-ylidenemalonate**

77 $C_{12}H_{18}O_4S_2$ White crystals.

78 **Identification**—Determine the absorption spectrum of a
79 solution of diisopropyl 1,3-dithiolan-2-ylidenemalonate in
80 methanol (1 in 125,000) as directed under Ultraviolet-visi-
81 ble Spectrophotometry <2.24>: it exhibits a maximum be-
82 tween 304 nm and 308 nm.

83 **Melting point** <2.60> 54 – 57°C

84 **Lanconazole** $C_{14}H_{10}ClN_3S_2$ [Same as the name-
85 sake monograph]

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