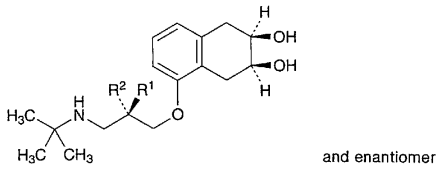
peaks being not less than 12.

System repeatability: When the test is repeated 6 times with 20 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak areas of mupirocin is not more than 1.0%.

Containers and storage Containers—Tight containers.

Nadolol

ナドロール



and enantiomer

$C_{17}H_{27}NO_4$: 309.40

R^1 = OH, R^2 = H

(2*RS*,3*SR*)-5-[3-(*tert*-Butylamino)-(*RS*)-2-hydroxypropyloxy]-1,2,3,4-tetrahydronaphthalene-2,3-diol

R^1 = H, R^2 = OH

(2*RS*,3*SR*)-5-[3-(*tert*-Butylamino)-(*SR*)-2-hydroxypropyloxy]-1,2,3,4-tetrahydronaphthalene-2,3-diol

[*42200-33-9*]

Nadolol, when dried, contains not less than 98.0% of $C_{17}H_{27}NO_4$.

Description Nadolol occurs as a white to yellow-brownish white crystalline powder.

It is freely soluble in methanol and in acetic acid (100), soluble in ethanol (95), and slightly soluble in water and in chloroform.

A solution of Nadolol in methanol (1 in 100) shows no optical rotation.

Melting point: about 137°C

Identification (1) Determine the absorption spectrum of a solution of Nadolol in methanol (1 in 5000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.

(2) Determine the infrared absorption spectrum of Nadolol, previously dried, as directed in the potassium bromide disk method under the Infrared Spectrophotometry: it exhibits absorption at the wave numbers of about 1585 cm^{-1}, 1460 cm^{-1}, 1092 cm^{-1}, 935 cm^{-1} and 770 cm^{-1}.

Purity (1) Heavy metals—Proceed with 1.0 g of Nadolol according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(2) Related substances—Dissolve 0.5 g of Nadolol in 10 mL of a mixture of methanol and chloroform (1:1), and use this solution as the sample solution. Perform the test with the sample solution as directed under the Thin-layer Chromatography. Spot 100 μL each of the sample solution and a mixture of methanol and chloroform (1:1) as a control solution with 25 mm each of width at an interval of about 10 mm on the starting line of a plate 0.25 mm in thickness of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of acetone, chloroform and diluted ammonia TS (1 in 3) (8:1:1) to a distance of about 15 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm), and confirm the positions of the principal spot and the spots other than the principal spot from the sample solution. Scratch and collect the silica gel of the positions of the plate corresponding to the principal spot and the spots other than the principal spot. To the silica gel collected from the principal spot add exactly 30 mL of ethanol (95), and to the silica gel from the spots other than the principal spot add exactly 10 mL of ethanol (95). After shaking them for 60 minutes, centrifuge, and determine the absorbances of these supernatant liquids at 278 nm as directed under the Ultraviolet-visible Spectrophotometry. Separately, proceed in the same manner with each position of the silica gel from the control solution corresponding to the principal spot and the spots other than the principal spot of the sample solution, and perform a blank determination to make correction. Amount of the related substances calculated by the following equation is not more than 2.0%.

$$\text{Amount (\%) of related substances} = \frac{A_b}{A_b + 3A_a} \times 100$$

A_a: Corrected absorbance of the principle spot.

A_b: Corrected absorbance of the spots other than the principle spot.

Loss on drying Not more than 1.0% (1 g, in vacuum, 60°C, 3 hours).

Residue on ignition Not more than 0.10% (1 g).

Isomer ratio Prepare a paste with 0.01 g of Nadolol as directed in the paste method under Infrared Spectrophotometry so that its transmittance at an absorption band at a wave number of about 1585 cm^{-1} is 25 to 30%, and determine the infrared absorption spectrum between 1600 cm^{-1} and 1100 cm^{-1}. Obtain the absorbances, A_{1265} and A_{1250}, from the transmittances, T_{1265} and T_{1250}, at wave numbers of about 1265 cm^{-1} (racemic substance A) and 1250 cm^{-1} (racemic substance B), respectively: the ratio A_{1265}/A_{1250} is between 0.72 and 1.08.

Assay Weigh accurately about 0.28 g of Nadolol, previously dried, dissolve in 50 mL of acetic acid (100), and titrate with 0.1 mol/L perchloric acid VS until the color of the solution changes from purple through blue to green-blue (indicator: 3 drops of crystal violet TS). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
= 30.941 mg of $C_{17}H_{27}NO_4$

Containers and storage Containers—Tight containers.
Storage—Light-resistant.