

Viscosity (2.2.9): 90 per cent to 110 per cent of the nominal kinematic viscosity stated on the label, determined at 25 °C.

Mineral oils. Place 2 g in a test-tube and examine in ultraviolet light at 365 nm. The fluorescence is not more intense than that of a solution containing 0.1 ppm of *quinine sulphate R* in 0.005 M sulphuric acid examined in the same conditions.

Phenylated compounds. Dissolve 5.0 g with shaking in 10 ml of *cyclohexane R*. At wavelengths from 250 nm to 270 nm, the absorbance (2.2.25) of the solution is not greater than 0.2.

Heavy metals: maximum 5 ppm.

Mix 1.0 g with *methylene chloride R* and dilute to 20 ml with the same solvent. Add 1.0 ml of a freshly prepared 0.02 g/l solution of *dithizone R* in *methylene chloride R*, 0.5 ml of *water R* and 0.5 ml of a mixture of 1 volume of *dilute ammonia R2* and 9 volumes of a 2 g/l solution of *hydroxylamine hydrochloride R*. At the same time, prepare a reference solution as follows: to 20 ml of *methylene chloride R* add 1.0 ml of a freshly prepared 0.02 g/l solution of *dithizone R* in *methylene chloride R*, 0.5 ml of *lead standard solution (10 ppm Pb) R* and 0.5 ml of a mixture of 1 volume of *dilute ammonia R2* and 9 volumes of a 2 g/l solution of *hydroxylamine hydrochloride R*. Immediately shake each solution vigorously for 1 min. Any red colour in the test solution is not more intense than that in the reference solution.

Volatile matter: maximum 0.3 per cent, for dimeticones with a nominal viscosity greater than 50 mm²s⁻¹, determined on 1.00 g by heating in an oven at 150 °C for 2 h. Carry out the test using a dish 60 mm in diameter and 10 mm deep.

LABELLING

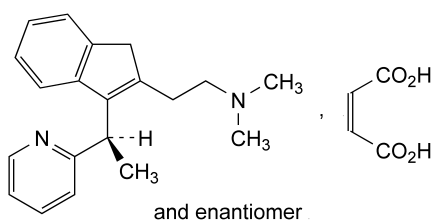
The label states:

- the nominal kinematic viscosity by a number placed after the name of the product,
- where applicable, that the product is intended for external use.

01/2008:1417
corrected 6.0

DIMETINDENE MALEATE

Dimetindeni maleas



C₂₄H₂₈N₂O₄
[3614-69-5]

M_r 408.5

DEFINITION

N,N-Dimethyl-2-[3-[(*RS*)-1-(pyridin-2-yl)ethyl]-1*H*-inden-2-yl]ethanamine (*Z*)-butenedioate.

Content: 99.0 per cent to 101.0 per cent (dried substance).

CHARACTERS

Appearance: white or almost white, crystalline powder.

Solubility: slightly soluble in water, soluble in methanol.

IDENTIFICATION

Infrared absorption spectrophotometry (2.2.24).

Preparation: discs.

Comparison: *dimetindene maleate CRS*.

TESTS

Solution S. Dissolve 0.20 g in *methanol R* and dilute to 20.0 ml with the same solvent.

Appearance of solution. Solution S is clear (2.2.1) and not more intensely coloured than Y₆ (2.2.2, *Method II*).

Optical rotation (2.2.7): –0.10° to +0.10°, determined on solution S.

Related substances. Gas chromatography (2.2.28).

Solvent mixture: *acetone R, methylene chloride R* (50:50 V/V).

Test solution. Dissolve 50.0 mg of the substance to be examined in the solvent mixture and dilute to 5.0 ml with the solvent mixture.

Reference solution (a). Dilute 1 ml of the test solution to 100.0 ml with the solvent mixture.

Reference solution (b). Dissolve 5.0 mg of *2-ethylpyridine R* (impurity A) in the solvent mixture and dilute to 50.0 ml with the solvent mixture. Dilute 10.0 ml of this solution to 100.0 ml with the solvent mixture.

Column:

- **material:** fused silica;
- **size:** *l* = 30 m, Ø = 0.32 mm;
- **stationary phase:** *polymethylphenylsiloxane R* (film thickness 0.25 µm).

Carrier gas: *helium for chromatography R*.

Linear velocity: about 30 cm/s.

Temperature:

	Time (min)	Temperature (°C)
Column	0 - 1	60
	1 - 34.3	60 → 260
	34.3 - 46.3	260
Injection port		240
Detector		260

Detection: flame ionisation.

Injection: 2 µl; inject via a split injector with a split flow of 30 ml/min.

Run time: 1.3 times the retention time of dimetindene.

Elution order: impurity A and maleic acid appear during the first 8 min.

System suitability: reference solution (a):

- **symmetry factor:** maximum 1.3 for the principal peak.

Limits:

- **impurity A:** not more than the area of the corresponding peak in the chromatogram obtained with reference solution (b) (0.1 per cent);
- **impurities B, C, D, E, F, G, H, I:** for each impurity, not more than 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.2 per cent);
- **sum of impurities other than A:** not more than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.5 per cent);
- **disregard limit:** 0.05 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.05 per cent); disregard the peak due to maleic acid.

Loss on drying (2.2.32): maximum 0.1 per cent, determined on 1.000 g by drying in an oven at 105 °C for 2 h.

Sulphated ash (2.4.14): maximum 0.1 per cent, determined on 1.0 g.

ASSAY

Dissolve 0.150 g in 80 ml of *anhydrous acetic acid R*. Titrate with 0.1 M perchloric acid, determining the end-point potentiometrically (2.2.20).

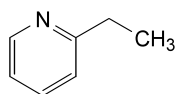
1 ml of 0.1 M perchloric acid is equivalent to 20.43 mg of $C_{24}H_{45}N_2O_8$.

STORAGE

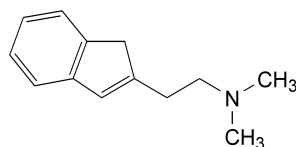
Protected from light.

IMPURITIES

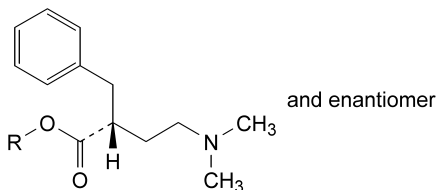
Specified impurities: A, B, C, D, E, F, G, H, I.



A. 2-ethylpyridine,

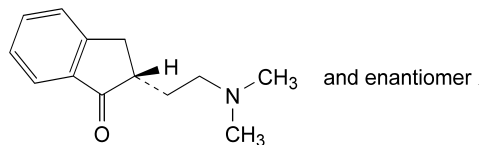


B. 2-(1*H*-inden-2-yl)-*N,N*-dimethylethanamine,

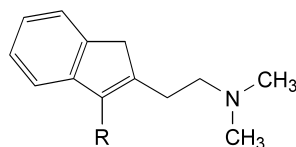


C. R = C_2H_5 : ethyl (2*RS*)-2-benzyl-4-(dimethylamino)butanoate,

D. R = H: (2*RS*)-2-benzyl-4-(dimethylamino)butanoic acid,

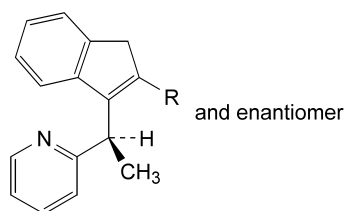


E. (2*RS*)-2-[2-(dimethylamino)ethyl]indan-1-one,



F. R = $[CH_2]_3-CH_3$: 2-(3-butyl-1*H*-inden-2-yl)-*N,N*-dimethylethanamine,

G. R = C_6H_5 : *N,N*-dimethyl-2-(3-phenyl-1*H*-inden-2-yl)ethanamine,



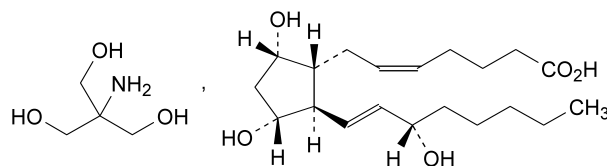
H. R = $CH=CH_2$: 2-[(1*RS*)-1-(2-ethenyl-1*H*-inden-3-yl)ethyl]pyridine,

I. R = $CH_2-CH_2-NH-CH_3$: *N*-methyl-2-[3-[(1*RS*)-1-(pyridin-2-yl)ethyl]-1*H*-inden-2-yl]ethanamine.

01/2008:1312

DINOPROST TROMETAMOL

Dinoprostum trometamololum



$C_{24}H_{45}NO_8$
[38562-01-5]

M_r 475.6

DEFINITION

Trometamol (*Z*)-7-[(1*R*,2*R*,3*R*,5*S*)-3,5-dihydroxy-2-[(*E*)-(3*S*)-3-hydroxyoct-1-enyl]cyclopentyl]hept-5-enoate (PGF_{2α}).

Content: 96.0 per cent to 102.0 per cent (anhydrous substance).

CHARACTERS

Appearance: white or almost white powder.

Solubility: very soluble in water, freely soluble in ethanol (96 per cent), practically insoluble in acetonitrile.

IDENTIFICATION

A. Specific optical rotation (2.2.7): + 19 to + 26 (anhydrous substance).

Dissolve 0.100 g in *ethanol (96 per cent) R* and dilute to 10.0 ml with the same solvent.

B. Infrared absorption spectrophotometry (2.2.24).

Comparison: *dinoprost trometamol CRS*.

TESTS

Related substances. Liquid chromatography (2.2.29).

Solvent mixture: *acetonitrile R*, *water R* (23:77 V/V).

Test solution. Dissolve 10.0 mg of the substance to be examined in the solvent mixture and dilute to 10.0 ml with the solvent mixture.

Reference solution (a). Degradation of dinoprost trometamol to impurity B. Dissolve 1 mg of the substance to be examined in 1 ml of the mobile phase and heat the solution on a water-bath at 85 °C for 5 min and cool.

Reference solution (b). Dilute 2.0 ml of the test solution to 20.0 ml with the solvent mixture. Dilute 2.0 ml of this solution to 20.0 ml with the solvent mixture.