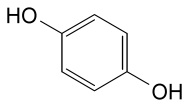
IMPURITIES

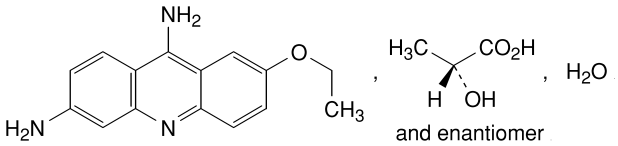


A. benzene-1,4-diol (hydroquinone).

01/2008:1591
corrected 6.0

ETHACRIDINE LACTATE MONOHYDRATE

Ethacridini lactas monohydricus



$C_{18}H_{21}N_3O_4,H_2O$ M_r 361.4
[1837-57-6]

DEFINITION

7-Ethoxyacridine-3,9-diamine (2*RS*)-2-hydroxypropanoate.

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

CHARACTERS

Appearance: yellow crystalline powder.

Solubility: sparingly soluble in water, very slightly soluble in alcohol, practically insoluble in methylene chloride.

IDENTIFICATION

First identification: A.

Second identification: B, C, D.

A. Infrared absorption spectrophotometry (*2.2.24*).
Comparison: *ethacridine lactate monohydrate CRS.*

B. Mix 0.1 ml of solution S (see Tests) and 100 ml of *water R*. The solution is greenish-yellow and shows a strong green fluorescence in ultraviolet light at 365 nm. Add 5 ml of *1 M hydrochloric acid*. The fluorescence remains.

C. To 0.5 ml of solution S add 1.0 ml of *water R*, 0.1 ml of a 10 g/l solution of *cobalt chloride R* and 0.1 ml of a 50 g/l solution of *potassium ferrocyanide R*. The solution is green.

D. To 50 ml of solution S add 10 ml of *dilute sodium hydroxide solution R*. Filter. To 5 ml of the filtrate, add 1 ml of *dilute sulphuric acid R*. 5 ml of the solution obtained gives the reaction of lactates (*2.3.1*).

TESTS

Solution S. Dissolve 2.0 g in *carbon dioxide-free water R* and dilute to 100.0 ml with the same solvent.

pH (*2.2.3*): 5.5 to 7.0 for solution S.

Related substances. Liquid chromatography (*2.2.29*).

Test solution. Dissolve 10.0 mg of the substance to be examined in the mobile phase and dilute to 25.0 ml with the mobile phase.

Reference solution (a). Dilute 1.0 ml of test solution to 100.0 ml with the mobile phase.

Reference solution (b). Dilute 1.0 ml of reference solution (a) to 10.0 ml with the mobile phase.

Column:
- *size*: *l* = 0.25 m, Ø = 4.6 mm,
- *stationary phase*: *octadecylsilyl silica gel for chromatography R* (5 µm).

Mobile phase: dissolve 1.0 g of *sodium octanesulphonate R* in a mixture of 300 ml of *acetonitrile R* and 700 ml of *phosphate buffer solution pH 2.8 R*.

Flow rate: 1 ml/min.

Detection: spectrophotometer at 268 nm.

Injection: 10 µl.

Run time: 3 times the retention time of ethacridine.

Retention time: ethacridine = about 15 min.

Limits:
- *any impurity*: not more than 3 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.3 per cent),
- *total*: not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (1 per cent),
- *disregard limit*: 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.05 per cent).

Heavy metals (*2.4.8*): maximum 50 ppm.

1.0 g complies with limit test F. Prepare the standard using 5.0 ml of *lead standard solution (10 ppm Pb) R*.

Loss on drying (*2.2.32*): 4.5 per cent to 5.5 per cent, determined on 1.000 g by drying in an oven *in vacuo* at 105 °C.

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

ASSAY

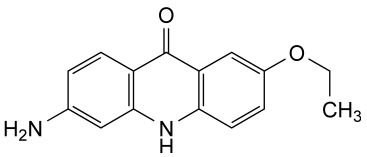
Dissolve 0.270 g in 5.0 ml of *anhydrous formic acid R*. Add 60.0 ml of *acetic anhydride R* and titrate with *0.1 M perchloric acid*, determining the end-point potentiometrically (*2.2.20*).

1 ml of *0.1 M perchloric acid* is equivalent to 34.34 mg of $C_{18}H_{21}N_3O_4$.

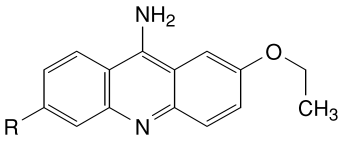
STORAGE

Protected from light.

IMPURITIES



A. 6-amino-2-ethoxyacridin-9(10*H*)-one,



B. R = Cl: 6-chloro-2-ethoxyacridin-9-amine,

C. R = O-CH_2-CH_2-OH: 2-[(9-amino-7-ethoxyacridin-3-yl)oxy]ethanol.