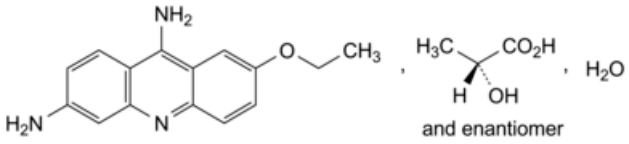
Edition: BP 2025 (Ph. Eur. 11.6 update)

Ethacridine Lactate Monohydrate

General Notices

(Ph. Eur. monograph 1591)



$C_{18}H_{21}N_3O_4,H_2O$ 361.4 *6402-23-9*

Action and use

Antiseptic.

Ph Eur

DEFINITION

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

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 ethanol (96 per cent), practically insoluble in methylene chloride.

IDENTIFICATION

First identification: A.

Second identification: B, C.

A. Infrared absorption spectrophotometry (2.2.24).

Comparison *ethacridine lactate monohydrate CRS*.

B. Thin-layer chromatography (*2.2.27*).

Test solution Dissolve 5 mg of the substance to be examined in 2 mL of *water R* and dilute to 10 mL with *methanol R*.

Reference solution Dissolve 5 mg of *ethacridine lactate monohydrate CRS* in 2 mL of *water R* and dilute to 10 mL with *methanol R*.

Plate *TLC silica gel F_{254} plate R*.

Mobile phase *glacial acetic acid R*, *water R*, *butanol R* (17:17:66 *V/V/V*).

Application 2 µL; the volume can be adapted based on the type of plate used.

Development Over 2/3 of the plate.

Drying At 100-105 °C.

Detection A Examine in daylight.

Results A The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution.

Detection B Examine in ultraviolet light at 254 nm and at 366 nm.

Results B The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution.

C. To 50 mL of solution S (see Tests) add 10 mL of *dilute sodium hydroxide solution R*. Filter. To 5 mL of the filtrate, add 1 mL of *dilute sulfuric 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 the 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*: *base-deactivated end-capped octadecylsilyl silica gel for chromatography R* (5 µm).

Mobile phase Dissolve 1.0 g of *sodium octanesulfonate 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).

Loss on drying (*2.2.32*)

4.5 per cent to 5.5 per cent, determined on 1.000 g by drying *in vacuo* at 105 °C.

Sulfated ash (*2.4.14*)

Maximum 0.1 per cent, determined on 1.0 g.

ASSAY

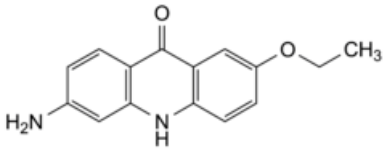
Dissolve 0.270 g in 5.0 mL of *anhydrous formic acid R*. Add 60.0 mL of *acetic anhydride R* and titrate with *0.1 M perchloric acid*, determining the end-point potentiometrically (*2.2.20*).

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

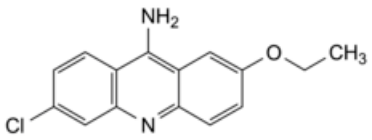
STORAGE

Protected from light.

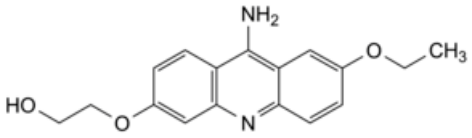
IMPURITIES



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



B. 6-chloro-2-ethoxyacridin-9-amine,



C. 2-[(9-amino-7-ethoxyacridin-3-yl)oxy]ethan-1-ol.

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