

Sulphates (2.4.13). Dissolve 0.2 g in 5 ml of *alcohol R* and dilute to 20 ml with *distilled water R*. 15 ml of the solution complies with the limit test for sulphates (0.1 per cent).

Heavy metals (2.4.8). 1.0 g complies with limit test C for heavy metals (20 ppm). Prepare the standard using 2 ml of *lead standard solution (10 ppm Pb R)*.

Water (2.5.12). Not more than 1.0 per cent, determined on 1.000 g by the semi-micro determination of water.

Sulphated ash (2.4.14). Not more than 0.1 per cent, determined on 1.0 g.

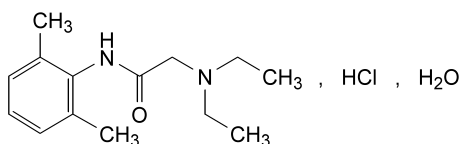
ASSAY

To 0.200 g add 50 ml of *anhydrous acetic acid R* and stir until dissolution is complete. 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 23.43 mg of $C_{14}H_{23}ClN_2O$.

01/2005:0227

LIDOCAINE HYDROCHLORIDE

Lidocaini hydrochloridum

 $C_{14}H_{23}ClN_2O \cdot H_2O$ M_r 288.8

DEFINITION

Lidocaine hydrochloride contains not less than 99.0 per cent and not more than the equivalent of 101.0 per cent of 2-(diethylamino)-*N*-(2,6-dimethylphenyl)acetamide hydrochloride, calculated with reference to the anhydrous substance.

CHARACTERS

A white, crystalline powder, very soluble in water, freely soluble in alcohol.

IDENTIFICATION

First identification: A, B, F.

Second identification: A, C, D, E, F.

- Melting point (2.2.14): 74 °C to 79 °C, determined without previous drying.
- Examine by infrared absorption spectrophotometry (2.2.24), comparing with the spectrum obtained with *lidocaine hydrochloride CRS*.
- Dissolve 0.2 g in 10 ml of *water R* and add 10 ml of *picric acid solution R*. The precipitate, washed with *water R* and dried, melts (2.2.14) at about 230 °C.
- To about 5 mg add 0.5 ml of *fuming nitric acid R*. Evaporate to dryness on a water-bath, cool and dissolve the residue in 5 ml of *acetone R*. Add 0.2 ml of *alcoholic potassium hydroxide solution R*. A green colour is produced.
- To 5 ml of solution S (see Tests) add 5 ml of *water R* and make alkaline with *dilute sodium hydroxide solution R*. Collect the precipitate on a filter and wash with *water R*. Dissolve half of the precipitate in 1 ml of *alcohol R* and add 0.5 ml of a 100 g/l solution of *cobalt nitrate R*. A bluish-green precipitate is formed.
- It gives reaction (a) of chlorides (2.3.1).

TESTS

Solution S. Dissolve 1.0 g in *carbon dioxide-free water R* and dilute to 20 ml with the same solvent.

Appearance of solution. Solution S is clear (2.2.1) and colourless (2.2.2, *Method II*).

pH (2.2.3). Dilute 1 ml of solution S to 10 ml with *carbon dioxide-free water R*. The pH of the solution is 4.0 to 5.5.

Impurity A

Solution (a). Dissolve 0.25 g of the substance to be examined in *methanol R* and dilute to 10 ml with the same solvent. This solution is used to prepare the test solution.

Solution (b). Dissolve 50 mg of *2,6-dimethylaniline R* in *methanol R* and dilute to 100 ml with the same solvent. Dilute 1 ml of the solution to 100 ml with *methanol R*. This solution is used to prepare the standard.

Using three flat-bottomed tubes, place in the first 2 ml of solution (a), in the second 1 ml of solution (b) and 1 ml of *methanol R* and in the third 2 ml of *methanol R* (used to prepare a blank). To each tube add 1 ml of a freshly prepared 10 g/l solution of *dimethylaminobenzaldehyde R* in *methanol R* and 2 ml of *glacial acetic acid R* and allow to stand at room temperature for 10 min. The intensity of the yellow colour of the test solution is between that of the blank and that of the standard (100 ppm).

Heavy metals (2.4.8). Dissolve 1.0 g in *water R* and dilute to 25 ml with the same solvent. Carry out the prefiltration. 10 ml of the prefiltrate complies with limit test E for heavy metals (5 ppm). Prepare the standard using 2 ml of *lead standard solution (1 ppm Pb R)*.

Water (2.5.12): 5.5 per cent to 7.0 per cent, determined on 0.25 g by the semi-micro determination of water.

Sulphated ash (2.4.14). Not more than 0.1 per cent, determined on 1.0 g.

ASSAY

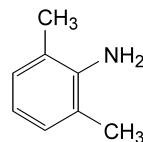
Dissolve 0.220 g in 50 ml of *alcohol R* and add 5.0 ml of *0.01 M hydrochloric acid*. Carry out a potentiometric titration (2.2.20), using *0.1 M sodium hydroxide*. Read the volume added between the 2 inflexion points.

1 ml of *0.1 M sodium hydroxide* is equivalent to 27.08 mg of $C_{14}H_{23}ClN_2O$.

STORAGE

Store protected from light.

IMPURITIES



A. 2,6-dimethylaniline.

01/2005:0957

LIME FLOWER

Tiliae flos

DEFINITION

Lime flower consists of the whole, dried inflorescence of *Tilia cordata* Miller, of *Tilia platyphyllos* Scop., of *Tilia × vulgaris* Heyne or a mixture of these.