Calculate the percentage content of cetyl alcohol using the following expression:

$$S_A \frac{100 \times m_H}{S_{Ha(corr)} \times m}$$

S_A = area of the peak due to cetyl alcohol in the chromatogram obtained with test solution (a),

m_H = mass of the internal standard in test solution (a), in milligrams,

$S_{Ha(corr)}$ = corrected area of the peak due to the internal standard in the chromatogram obtained with test solution (a),

m = mass of the substance to be examined in test solution (a), in milligrams.

Calculate the percentage content of stearyl alcohol using the following expression:

$$S_B \frac{100 \times m_H}{S_{Ha(corr)} \times m}$$

S_B = area of the peak due to stearyl alcohol in the chromatogram obtained with test solution (a).

The percentage content of cetostearyl alcohol corresponds to the sum of the percentage content of cetyl alcohol and of stearyl alcohol.

Sodium laurilsulfate. Disperse 0.300 g in 25 ml of *methylene chloride R*. Add 50 ml of *water R* and 10 ml of *dimidium bromide-sulphan blue mixed solution R*. Titrate with *0.004 M benzethonium chloride*, using sonication, heating, and allowing the layers to separate before each addition, until the colour of the lower layer changes from pink to grey.

1 ml of *0.004 M benzethonium chloride* is equivalent to 1.154 mg of sodium laurilsulfate.

LABELLING

The label states, where applicable, the name and concentration of any added buffer.

01/2008:1085

CETOSTEARYL ISONONANOATE

Cetostearylis isononanoas

DEFINITION

Mixture of esters of cetostearyl alcohol with isononanoic acid, mainly 3,5,5-trimethylhexanoic acid.

CHARACTERS

Appearance: clear, colourless or slightly yellowish liquid.

Solubility: practically insoluble in water, soluble in ethanol (96 per cent) and in light petroleum, miscible with fatty oils and with liquid paraffins.

Viscosity: 15 mPa·s to 30 mPa·s.

Relative density: 0.85 to 0.86.

Refractive index: 1.44 to 1.45.

IDENTIFICATION

A. On cooling, turbidity occurs below 15 °C.

B. Saponification value (see Tests).

C. Infrared absorption spectrophotometry (*2.2.24*).

Comparison: *Ph. Eur. reference spectrum of cetostearyl isononanoate.*

TESTS

Appearance. The substance to be examined is clear (*2.2.1*) and not more intensely coloured than reference solution Y_6 (*2.2.2, Method I*).

Acid value (*2.5.1*): maximum 1.0, determined on 5.0 g.

Hydroxyl value (*2.5.3, Method A*): maximum 5.0.

Iodine value (*2.5.4, Method A*): maximum 1.0.

Saponification value (*2.5.6*): 135 to 148, determined on 1.0 g.

Heavy metals (*2.4.8*): maximum 10 ppm.

2.0 g complies with test D. Prepare the reference solution using 2 ml of *lead standard solution (10 ppm Pb) R*.

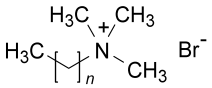
Water (*2.5.12*): maximum 0.2 per cent, determined on 10.0 g.

Total ash (*2.4.16*): maximum 0.2 per cent, determined on 2.0 g.

01/2008:0378
corrected 6.0

CETRIMIDE

Cetrimidum



DEFINITION

Cetrimide consists of trimethyltetradecylammonium bromide and may contain smaller amounts of dodecyl- and hexadecyl-trimethylammonium bromides.

Content: 96.0 per cent to 101.0 per cent of alkyltrimethylammonium bromides, calculated as $C_{17}H_{38}BrN$ (M_r 336.4) (dried substance).

CHARACTERS

Appearance: white or almost white, voluminous, free-flowing powder.

Solubility: freely soluble in water and in alcohol.

IDENTIFICATION

A. Dissolve 0.25 g in *alcohol R* and dilute to 25.0 ml with the same solvent. At wavelengths from 260 nm to 280 nm, the absorbance (*2.2.25*) of the solution has a maximum of 0.05.

B. Dissolve about 5 mg in 5 ml of *buffer solution pH 8.0 R*. Add about 10 mg of *potassium ferricyanide R*. A yellow precipitate is formed. Prepare a blank in the same manner but omitting the substance to be examined: a yellow solution is observed but no precipitate is formed.

C. Solution S (see Tests) froths copiously when shaken.

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

Test solution. Dissolve 0.10 g of the substance to be examined in *water R* and dilute to 5 ml with the same solvent.

Reference solution. Dissolve 0.10 g of *trimethyltetradecylammonium bromide CRS* in *water R* and dilute to 5 ml with the same solvent.

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

Mobile phase: *acetone R*, 270 g/l solution of *sodium acetate R*, *methanol R* (20:35:45 *V/V/V*).

Application: 1 µl.

Development: over a path of 12 cm.

Drying: in a current of hot air.

Detection: allow to cool; expose the plate to iodine vapour and examine in daylight.

Result: 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.

E. It gives reaction (a) of bromides (*2.3.1*).

TESTS

Solution S. Dissolve 2.0 g in *carbon dioxide-free water R* and dilute to 100 ml with the same solvent.

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

Acidity or alkalinity. To 50 ml of solution S add 0.1 ml of *bromocresol purple solution R*. Not more than 0.1 ml of *0.1 M hydrochloric acid* or *0.1 M sodium hydroxide* is required to change the colour of the indicator.

Amines and amine salts. Dissolve 5.0 g in 30 ml of a mixture of 1 volume of *1 M hydrochloric acid* and 99 volumes of *methanol R* and add 100 ml of *2-propanol R*. Pass a stream of *nitrogen R* slowly through the solution. Gradually add 15.0 ml of *0.1 M tetrabutylammonium hydroxide* and record the potentiometric titration curve (*2.2.20*). If the curve shows 2 points of inflexion, the volume of titrant added between the 2 points is not greater than 2.0 ml.

Loss on drying (*2.2.32*): maximum 2.0 per cent, determined on 1.000 g by drying in an oven at 105 °C for 2 h.

Sulphated ash (*2.4.14*): maximum 0.5 per cent, determined on 1.0 g.

ASSAY

Dissolve 2.000 g in *water R* and dilute to 100.0 ml with the same solvent. Transfer 25.0 ml of the solution to a separating funnel, add 25 ml of *chloroform R*, 10 ml of *0.1 M sodium hydroxide* and 10.0 ml of a freshly prepared 50 g/l solution of *potassium iodide R*. Shake, allow to separate and discard the chloroform layer. Shake the aqueous layer with 3 quantities, each of 10 ml, of *chloroform R* and discard the chloroform layers. Add 40 ml of *hydrochloric acid R*, allow to cool and titrate with *0.05 M potassium iodate* until the deep brown colour is almost discharged. Add 2 ml of *chloroform R* and continue the titration, shaking vigorously, until the colour of the chloroform layer no longer changes. Carry out a blank titration on a mixture of 10.0 ml of the freshly prepared 50 g/l solution of *potassium iodide R*, 20 ml of *water R* and 40 ml of *hydrochloric acid R*.

1 ml of *0.05 M potassium iodate* is equivalent to 33.64 mg of $C_{17}H_{38}BrN$.

01/2008:0540

CETYL ALCOHOL

Alcohol cetylicus

DEFINITION

Mixture of solid alcohols, mainly hexadecan-1-ol ($C_{16}H_{34}O$; M_r 242.4), of animal or vegetable origin.

Content: minimum 95.0 per cent of $C_{16}H_{34}O$.

CHARACTERS

Appearance: white or almost white, unctuous mass, powder, flakes or granules.

Solubility: practically insoluble in water, freely soluble or sparingly soluble in ethanol (96 per cent). When melted, it is miscible with vegetable and animal oils, with liquid paraffin and with melted wool fat.

IDENTIFICATION

Examine the chromatograms obtained in the assay.

Results: the principal peak in the chromatogram obtained with the test solution is similar in retention time to the principal peak in the chromatogram obtained with reference solution (a).

TESTS

Appearance of solution. The solution is clear (*2.2.1*) and not more intensely coloured than reference solution B_6 (*2.2.2, Method II*).

Dissolve 0.50 g in 20 ml of boiling *ethanol (96 per cent) R*. Allow to cool.

Melting point (*2.2.14*): 46 °C to 52 °C.

Acid value (*2.5.1*): maximum 1.0.

Hydroxyl value (*2.5.3, Method A*): 218 to 238.

Iodine value (*2.5.4, Method A*): maximum 2.0.

Dissolve 2.00 g in *methylene chloride R* and dilute to 25 ml with the same solvent.

Saponification value (*2.5.6*): maximum 2.0.

ASSAY

Gas chromatography (*2.2.28*): use the normalisation procedure.

Test solution. Dissolve 0.100 g of the substance to be examined in *ethanol (96 per cent) R* and dilute to 10.0 ml with the same solvent.

Reference solution (a). Dissolve 50 mg of *cetyl alcohol CRS* in *ethanol (96 per cent) R* and dilute to 5 ml with the same solvent.

Reference solution (b). Dissolve 50 mg of *stearyl alcohol R* in *ethanol (96 per cent) R* and dilute to 10 ml with the same solvent.

Reference solution (c). Mix 1 ml of reference solution (a) and 1 ml of reference solution (b) and dilute to 10 ml with *ethanol (96 per cent) R*.

Column:

– *size*: *l* = 30 m, Ø = 0.32 mm,

– *stationary phase*: *poly(dimethyl)siloxane R* (1 µm).

Carrier gas: *helium for chromatography R*.

Flow rate: 1 ml/min.

Split ratio: 1:100.

Temperature:

	Time (min)	Temperature (°C)
Column	0 - 20	150 → 250
	20 - 40	250
Injection port		250
Detector		250

Detection: flame ionisation.

Injection: 1 µl of the test solution and reference solutions (a) and (c).

System suitability: reference solution (c):

– *resolution*: minimum 5.0 between the peaks due to cetyl alcohol and stearyl alcohol.

Calculate the percentage content of $C_{16}H_{34}O$.