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
corrected 10.0

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*: *methylpolysiloxane 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 $C_{16}H_{34}O$.

01/2020:1906

CETYL PALMITATE

Cetylis palmitas

DEFINITION

Mixture of esters of C_{14}-C_{18} alcohols with lauric (dodecanoic), myristic (tetradecanoic), palmitic (hexadecanoic) and stearic (octadecanoic) acids ('Cetyl esters wax').

Content (expressed as hexadecyl hexadecanoate): 10.0 per cent to 20.0 per cent for Cetyl palmitate 15, 60.0 per cent to 70.0 per cent for Cetyl palmitate 65 and minimum 90.0 per cent for Cetyl palmitate 95.

CHARACTERS

Appearance: white or almost white, waxy plates, flakes or powder.

Solubility: practically insoluble in water, soluble in boiling anhydrous ethanol and in methylene chloride, slightly soluble in light petroleum, practically insoluble in anhydrous ethanol.

mp: about 45 °C for Cetyl palmitate 15 and Cetyl palmitate 65 and about 52 °C for Cetyl palmitate 95.

IDENTIFICATION

A. It complies with the limits of the assay and the chromatogram obtained with the test solution shows the typical main peak(s).

B. Saponification value (see Tests).

TESTS

Appearance of solution. The solution is not more intensely coloured than reference solution Y_6 (*2.2.2, Method II*).

Dissolve 4.0 g in *methylene chloride R* and dilute to 20 mL with the same solvent.

Acid value (*2.5.1*): maximum 4.0.

Dissolve 10.0 g in 50 mL of the solvent mixture described by heating under reflux on a water-bath for 5 min.

Hydroxyl value (*2.5.3, Method A*): maximum 20.0.

Carry out the titration at a temperature between 55 °C and 70 °C, shaking the flask towards the end of the titration.

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

Saponification value (*2.5.6*): 105 to 120.

Heat under reflux for 2 h.