01/2008:1906

CETYL PALMITATE

Cetylis palmitas

DEFINITION

Mixture of C_{14}-C_{18} esters of 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.

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

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

Heat under reflux for 2 h.

Alkaline impurities. Dissolve 2.0 g 'with gentle heating' in a mixture of 1.5 ml of *ethanol (96 per cent) R* and 3 ml of *toluene R*. Add 0.05 ml of a 0.4 g/l solution of *bromophenol blue R* in *ethanol (96 per cent) R*. Not more than 0.4 ml of *0.01 M hydrochloric acid* is required to change the colour of the solution to yellow.

Nickel (*2.4.31*): maximum 1 ppm.

Water (*2.5.12*): maximum 0.3 per cent, determined on 1.0 g using a mixture of equal volumes of *anhydrous methanol R* and *methylene chloride R* as solvent.

Total ash (*2.4.16*): maximum 0.2 per cent, determined on 1.0 g.

ASSAY

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

Test solution. Dissolve 20.0 mg of the substance to be examined in *hexane R* and dilute to 20.0 ml with the same solvent.

Reference solution (a). Dissolve 20.0 mg of *cetyl palmitate 95 CRS* in *hexane R* and dilute to 20.0 ml with the same solvent.

Reference solution (b). Dissolve 20.0 mg of *cetyl palmitate 15 CRS* in *hexane R* and dilute to 20.0 ml with the same solvent.

Column:

- *material*: stainless steel;
- *size*: *l* = 10 m, Ø = 0.53 mm;
- *stationary phase*: *poly(dimethyl)siloxane R* (film thickness 2.65 µm).

Carrier gas: *helium for chromatography R*.

Flow rate: 6.5 ml/min.

Split ratio: 1:10.

Temperature:

	Time (min)	Temperature (°C)
Column	0 - 10	100 → 300
	10 - 15	300
Injection port		350
Detector		350

Detection: flame ionisation.

Injection: 1 µl.

Relative retention with reference to cetyl palmitate (retention time = about 9 min): cetyl alcohol = about 0.3; palmitic acid = about 0.4; lauric ester = about 0.8; myristic ester = about 0.9; stearic ester = about 1.1.

System suitability: reference solution (b):

- *resolution*: minimum of 1.5 between the peaks due to cetyl palmitate and cetyl stearate.

STORAGE

At a temperature not exceeding 25 °C.

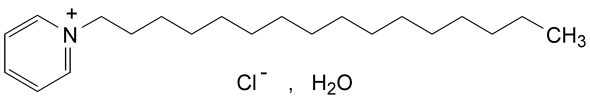
LABELLING

The label states the type of cetyl palmitate.

01/2008:0379
corrected 6.0

CETYLPYRIDINIUM CHLORIDE

Cetylpyridinii chloridum



$C_{21}H_{38}ClN,H_2O$ M_r 358.0
[6004-24-6]

DEFINITION

Cetylpyridinium chloride contains not less than 96.0 per cent and not more than the equivalent of 101.0 per cent of 1-hexadecylpyridinium chloride, calculated with reference to the anhydrous substance.

CHARACTERS

A white or almost white powder, slightly soapy to the touch, soluble in water and in alcohol. An aqueous solution froths copiously when shaken.

IDENTIFICATION

First identification: B, D.