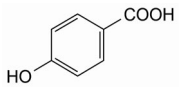
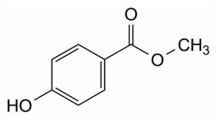
IMPURITIES

Specified impurities: A.

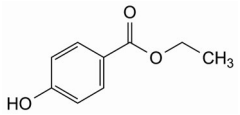
Other detectable impurities (the following substances would, if present at a sufficient level, be detected by one or other of the tests in the monograph. They are limited by the general acceptance criterion for other/unspecified impurities and/or by the general monograph *Substances for pharmaceutical use (2034)*. It is therefore not necessary to identify these impurities for demonstration of compliance. See also *5.10. Control of impurities in substances for pharmaceutical use*): *B, C, D.*



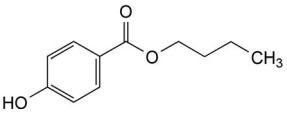
A. 4-hydroxybenzoic acid,



B. methyl 4-hydroxybenzoate (methyl parahydroxybenzoate),



C. ethyl 4-hydroxybenzoate (ethyl parahydroxybenzoate),

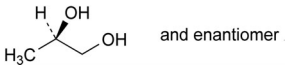


D. butyl 4-hydroxybenzoate (butyl parahydroxybenzoate).

01/2017:0430

PROPYLENE GLYCOL

Propylenglycolum



$C_3H_8O_2$ M_r 76.1

[57-55-6]

DEFINITION

Propylene glycol is (*RS*)-propane-1,2-diol.

CHARACTERS

A viscous, clear, colourless, hygroscopic liquid, miscible with water and with ethanol (96 per cent).

IDENTIFICATION

A. Relative density (see Tests).

B. Refractive index (see Tests).

C. Boiling point (*2.2.12*): 184 °C to 189 °C.

D. To 0.5 mL add 5 mL of *pyridine R* and 2 g of finely ground *nitrobenzoyl chloride R*. Boil for 1 min and pour into 15 mL of cold *water R* with shaking. Filter, wash the precipitate with 20 mL of a saturated solution of *sodium hydrogen carbonate R* and then with *water R* and dry. Dissolve in boiling *ethanol (80 per cent V/V) R* and filter the hot solution. On cooling, crystals are formed which, after drying at 100-105 °C, melt (*2.2.14*) at 121 °C to 128 °C.

TESTS

Appearance. It is clear (*2.2.1*) and colourless (*2.2.2, Method II*).

Relative density (*2.2.5*): 1.035 to 1.040.

Refractive index (*2.2.6*): 1.431 to 1.433.

Acidity. To 10 mL add 40 mL of *water R* and 0.1 mL of *bromothymol blue solution R1*. The solution is greenish-yellow. Not more than 0.05 mL of *0.1 M sodium hydroxide* is required to change the colour of the indicator to blue.

Oxidising substances. To 10 mL add 5 mL of *water R*, 2 mL of *potassium iodide solution R* and 2 mL of *dilute sulfuric acid R* and allow to stand in a ground-glass-stoppered flask protected from light for 15 min. Titrate with *0.05 M sodium thiosulfate*, using 1 mL of *starch solution R* as indicator. Not more than 0.2 mL of *0.05 M sodium thiosulfate* is required.

Reducing substances. To 1 mL add 1 mL of *dilute ammonia R1* and heat in a water-bath at 60 °C for 5 min. The solution is not yellow. Immediately add 0.15 mL of *0.1 M silver nitrate* and allow to stand for 5 min. The solution does not change its appearance.

Water (*2.5.12*). Not more than 0.2 per cent, determined on 5.00 g by the semi-micro determination of water.

Sulfated ash (*2.4.14*). Heat 50 g until it burns and ignite. Allow to cool. Moisten the residue with *sulfuric acid R* and ignite; repeat the operations. The residue weighs not more than 5 mg (0.01 per cent).

STORAGE

Store in an airtight container.

01/2016:2122

PROPYLENE GLYCOL DICAPRYLOCAPRATE

Propylenglycoli dicaprylocapras

DEFINITION

Propylene glycol diesters of saturated fatty acids, mainly caprylic (octanoic) acid and capric (decanoic) acid, of vegetable origin.

CHARACTERS

Appearance: almost colourless or light yellow, oily liquid.

Solubility: practically insoluble in water, soluble in fatty oils and in light petroleum, slightly soluble in anhydrous ethanol.

IDENTIFICATION

First identification: C, D.

Second identification: A, B, C, E.

A. Refractive index (*2.2.6*): 1.439 to 1.442.

B. Relative density (*2.2.5*): 0.910 to 0.930.

C. Viscosity (*2.2.9*): 9 mPa·s to 13 mPa·s.

D. Composition of fatty acids (see Tests).

E. Saponification value (see Tests).

TESTS

Appearance. The substance to be examined is clear (*2.2.1*) and not more intensely coloured than reference solution BY_6 (*2.2.2, Method II*).

Acid value (*2.5.1*): maximum 0.2.

Hydroxyl value (*2.5.3, Method A*): maximum 10.

Iodine value (*2.5.4*): maximum 1.0.