Quality standards

This text was updated in Ph. Eur. 11.6 (effective 01/01/2025)

Edition: BP 2025 (Ph. Eur. 11.6 update)

Octoxinol 10

General Notices

(Ph. Eur. monograph 1553)

Action and use

Excipient.

Ph Eur

DEFINITION

 α -[4-(2,4,4-Trimethylpentan-2-yl)phenyl]- ω -hydroxydeca(oxyethane-1,2-diyl).

Mixture consisting mainly of mono-octylphenyl ethers of macrogols corresponding to the formula $C_8H_{17}C_6H_4$ - $[OCH_2-CH_2]_n$ -OH where the average value of n is 10 $(C_{34}H_{62}O_{11}; M_r$ 646). It may contain free macrogols.

CHARACTERS

Appearance

Clear, colourless or light yellow, viscous liquid.

Solubility

Miscible with water, with ethanol (96 per cent) and with vegetable oils.

IDENTIFICATION

A. Infrared absorption spectrophotometry (2.2.24).

Comparison octoxinol 10 CRS.

Preparation Film between <u>sodium chloride R</u> plates.

B. Cloud point (see Tests).

TESTS

Acidity or alkalinity

Boil 1.0 g with 20 mL of <u>carbon dioxide-free water R</u> for 1 min, with constant stirring. Cool and filter. To 10 mL of the filtrate, add 0.05 mL of <u>bromothymol blue solution R1</u>. Not more than 0.5 mL of <u>0.01 M</u> <u>hydrochloric acid</u> or <u>0.01 M sodium hydroxide</u> is required to change the colour of the indicator.

Hydroxyl value (2.5.3, Method A)

85 to 101. Calculate the hydroxyl value using the following expression:

$$I_{ ext{OH}} \ = rac{28.05 \ (n_2 \ - \ n_1)}{m}$$

Cloud point

63 °C to 70 °C.

Dissolve 1.0 g in 99 g of <u>water R</u>. Transfer about 30 mL of the solution to a test-tube, heat on a water-bath and stir continuously until the solution becomes cloudy. Remove the test-tube from the water-bath (ensuring that the temperature does not increase more than 2 °C), and continue to stir. The cloud point is the temperature at which the solution becomes sufficiently clear that the entire thermometer bulb is plainly seen.

Ethylene oxide and dioxan (2.4.25)

Maximum 1 ppm of ethylene oxide and maximum 10 ppm of dioxan.

Water (2.5.12)

Maximum 0.5 per cent, determined on 2.00 g.

Total ash (2.4.16)

Maximum 0.4 per cent, determined on 1.0 g.

STORAGE

In an airtight container.

Ph Eur