01/2005:1082

MACROGOLGLYCEROL RICINOLEATE

Macrogolglyceroli ricinoleas

DEFINITION

Contains mainly ricinoleyl glycerol ethoxylated with 30 to 50 molecules of ethylene oxide (nominal value), with small amounts of macrogol ricinoleate and of the corresponding free glycols. It results from the reaction of castor oil with ethylene oxide.

CHARACTERS

Appearance: clear, yellow viscous liquid or semi-solid.

Solubility: freely soluble in water, very soluble in methylene chloride, freely soluble in alcohol.

Relative density: about 1.05.

Viscosity: 500 mPa·s to 800 mPa·s at 25 °C.

IDENTIFICATION

A. It complies with the test for iodine value (see Tests).

B. It complies with the test for saponification value (see Tests).

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

Test solution. To 1 g of the substance to be examined add 100 ml of a 100 g/l solution of *potassium hydroxide R* and boil under a reflux condenser for 30 min. Allow to cool. Acidify the solution with 20 ml of *hydrochloric acid R*. Shake the mixture with 50 ml of *ether R* and allow to stand until separation of the layers is obtained. Transfer the clear upper layer to a suitable tube, add 5 g of *anhydrous sodium sulphate R*, close the tube and allow to stand for 30 min. Filter and evaporate the filtrate to dryness on a water-bath. Dissolve 50 mg of the residue in 25 ml of *ether R*.

Reference solution. Dissolve 50 mg of *ricinoleic acid R* in *methylene chloride R* and dilute to 25 ml with the same solvent.

Plate: *TLC octadecylsilyl silica gel plate R*.

Mobile phase: *methylene chloride R, glacial acetic acid R, acetone R* (10:40:50 *V/V/V*).

Application: 2 µl.

Development: over a path of 8 cm.

Drying: in a current of cold air.

Detection: spray with an 80 g/l solution of *phosphomolybdic acid R* in *2-propanol R* and heat at 120 °C for 1-2 min.

Results: the principal spot in the chromatogram obtained with the test solution is similar in position and colour to the principal spot in the chromatogram obtained with the reference solution.

D. Place about 2 g of the substance to be examined in a test-tube and add 0.2 ml of *sulphuric acid R*. Close the tube using a stopper fitted with a glass tube bent twice at right angles. Heat the tube until white fumes appear. Collect the fumes in 1 ml of *mercuric chloride solution R*. A white precipitate is formed and the fumes turn a filter paper impregnated with *alkaline potassium tetraiodomercurate solution R* black.

TESTS

Solution S. Dissolve 5.0 g in *carbon dioxide-free water R* and dilute to 50 ml with the same solvent.

Appearance of solution. Solution S is not more opalescent than reference suspension III (*2.2.1*) and not more intensely coloured than reference solution BY_6 (*2.2.2, Method II*).

Alkalinity. Dissolve 2.0 g in a hot mixture of 10 ml of *water R* and 10 ml of *alcohol R*. Add 0.1 ml of *bromothymol blue solution R1*. Not more than 0.5 ml of *0.1 M hydrochloric acid* is required to change the colour of the indicator to yellow.

Acid value (*2.5.1*): maximum 2.0, determined on 5.0 g.

Hydroxyl value (*2.5.3, Method A*). See Table 1082.-1.

Iodine value (*2.5.4*): 25 to 35.

Saponification value (*2.5.6*). See Table 1082.-1.

Table 1082.-1

Ethylene oxide units per molecule (nominal value)	Hydroxyl value	Saponification value
30 - 35	65 - 82	60 - 75
50	48 - 68	38 - 52

Residual ethylene oxide and dioxan (*2.4.25*): maximum 1 ppm of residual ethylene oxide and 10 ppm of residual dioxan.

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

12 ml of solution S, filtered if necessary, complies with limit test A. Prepare the standard using *lead standard solution (1 ppm Pb) R*.

Water (*2.5.12*): maximum 3.0 per cent, determined on 2.000 g.

Total ash (*2.4.16*): maximum 0.3 per cent, determined on 2.0 g.

STORAGE

Store protected from light.

LABELLING

The label states the amount of ethylene oxide reacted with castor oil (nominal value).