



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

High-molecular-mass Macrogols



[General Notices](#)

(Ph. Eur. monograph 2444)

Ph Eur

DEFINITION

Mixtures of high-molecular-mass macrogols (also known as polyethylene oxides). The type of high-molecular-mass macrogol is defined by a number that indicates the nominal average molecular mass in the range of 100 000 to 7 000 000. A suitable stabiliser (e.g. butylhydroxytoluene) and a suitable flowability agent (e.g. silicon dioxide) may be added.

CHARACTERS

Appearance

White or almost white, free-flowing powder.

Solubility

Freely soluble in water.

mp

Minimum 65 °C.

IDENTIFICATION

A. Infrared absorption spectrophotometry ([2.2.24](#)).

Comparison [high-molecular-mass macrogol CRS](#).

B. Viscosity (see Tests).

TESTS

Solution S

Prepare a solution of the substance to be examined in a mixture of [carbon dioxide-free water R](#) and [2-propanol R](#) according to Table 2444.-1.

pH ([2.2.3](#))

6.0 to 10.0 for solution S.

Viscosity ([2.2.10](#))

Determine the dynamic viscosity of solution S at 25 °C using a rotating viscometer and a suitable spindle.

Table 2444.-1. – *Solution S and viscosity*

Nominal average molecular mass	Composition of solution S (g of substance / mL of carbon dioxide-free water R + mL of 2-propanol R)	Dynamic viscosity (mPa·s)	Rotation speed (r/min)
100 000	30 g / 570 + 125	12 - 50	50
200 000	30 g / 570 + 125	65 - 115	50
300 000	30 g / 570 + 125	600 - 1200	10
400 000	30 g / 570 + 125	2250 - 4500	2
600 000	30 g / 570 + 125	4500 - 8800	2
900 000	30 g / 570 + 125	8800 - 17 600	2
1 000 000	12 g / 588 + 125	400 - 800	10
2 000 000	12 g / 588 + 125	2000 - 4000	10
4 000 000	6 g / 594 + 125	1650 - 5500	2
5 000 000	6 g / 594 + 125	5500 - 7500	2
7 000 000	6 g / 594 + 125	7500 - 10 000	2

Ethylene oxide ([2.4.25, Method A](#))

Maximum 1 ppm.

Carry out the test with the following modifications.

Stock solution Dilute 0.5 mL of [ethylene oxide stock solution R2](#) to 10.0 mL with [propanol R](#). Dilute 1.0 mL of this solution to 50.0 mL with [propanol R](#).

Test solution Weigh 0.50 g (M_T) of the substance to be examined into a 10 mL vial (other sizes may be used depending on the operating conditions). Close and allow to stand at 70 °C for 30 min.

Reference solution (a) Weigh 0.50 g (M_R) of the substance to be examined into an identical 10 mL vial and add 10 µL of the stock solution. Close and homogenise, and allow to stand at 70 °C for 30 min.

Reference solution (b) To 0.50 mL of [ethylene oxide solution R3](#) in a 10 mL vial add 0.1 mL of a freshly prepared 10 mg/L solution of [acetaldehyde R](#). Close and homogenise, and allow to stand at 70 °C for 30 min.

Loss on drying (2.2.32)

Maximum 1.0 per cent, determined on 1.000 g by drying in an oven at 105 °C for 45 min.

Sulfated ash

Maximum 5.0 per cent, determined on 1.00 g.

Heat a silica crucible to redness for 30 min, allow to cool in a desiccator and weigh. Evenly distribute 1.00 g of the substance to be examined in the crucible and weigh. Dry at 100-105 °C for 1 h and ignite in a muffle furnace at 600 ± 25 °C, until the substance is thoroughly charred. Carry out the test for sulfated ash ([2.4.14](#)) on the residue obtained, starting from “Moisten the substance to be examined...”.

STORAGE

In an airtight container.

LABELLING

The label states the type of high-molecular-mass macrogol.

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