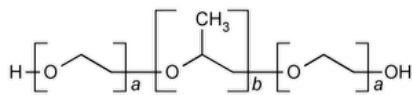


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Poloxamer



$\text{HO}(\text{C}_2\text{H}_4\text{O})_a(\text{C}_3\text{H}_6\text{O})_b(\text{C}_2\text{H}_4\text{O})_a\text{H}$
Oxirane, methyl-, polymer with oxirane;
 α -Hydro- ω -hydroxypoly(oxyethylene)_a-poly(oxypropylene)_b-poly(oxyethylene)_a block copolymer, in which *a* and *b* have the values shown in the following table:

Poloxamer	<i>a</i>	<i>b</i>
124	12	20
188	80	27
237	64	37
338	141	44
407	101	56

Polyethylene-polypropylene glycol
CAS RN®: 9003-11-6.

Change to read:

DEFINITION

Poloxamer is a synthetic block copolymer of ethylene oxide and propylene oxide. It is available in several types, conforming to the requirements shown in the following table.

Poloxamer	Physical Form	Average Molecular Weight	Weight (% Oxyethylene)	Unsaturation (mEq/g)
124	Liquid	2090–2360	46.7 ± 1.9	▲NMT 0.028▲ (NF 1-Dec-2021)
188	Solid	7680–9510	81.8 ± 1.9	▲NMT 0.034▲ (NF 1-Dec-2021)
237	Solid	6840–8830	72.4 ± 1.9	▲NMT 0.042▲ (NF 1-Dec-2021)
338	Solid	12,700–17,400	83.1 ± 1.7	▲NMT 0.039▲ (NF 1-Dec-2021)

Poloxamer	Physical Form	Average Molecular Weight	Weight (% Oxyethylene)	Unsaturation (mEq/g)
407	Solid	9840–14,600	73.2 ± 1.7	▲NMT 0.065▲ (NF 1-Dec-2021)

It may contain a suitable antioxidant.

IDENTIFICATION

• A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197F

Use a thin film of melted specimen if it is a solid. Use [USP Poloxamer Liquid RS](#) for Poloxamer 124, and use [USP Poloxamer Solid RS](#) for Poloxamer 188, 237, 338, and 407. Because of the differences in the ratios of copolymer composition, the intensity of some absorption bands may vary.

ASSAY

• AVERAGE MOLECULAR WEIGHT

Phthalic anhydride–pyridine solution: Dissolve 144 g of phthalic anhydride in freshly opened or freshly distilled pyridine containing less than 0.1% of water, and dilute with pyridine to 1000 mL. Protect from light, and allow to stand overnight. To verify that the *Phthalic anhydride–pyridine solution* has adequate strength, pipet 10 mL into a 250-mL conical flask, add 25 mL of pyridine and 50 mL of water, and after 15 min add 0.5 mL of a solution of phenolphthalein in pyridine (1 in 100), then titrate with 0.5 N sodium hydroxide VS: it consumes between 37.6 and 40.0 mL of 0.5 N sodium hydroxide.

Analysis: Weigh a suitable quantity, not exceeding 15 g, of Poloxamer, calculated by multiplying the average molecular weight by 0.004, into a glass-stoppered, 250-mL boiling flask. Carefully pipet 25 mL of *Phthalic anhydride–pyridine solution* into the flask, touching the tip of the drained pipet to the protrusion in the flask. Add a few glass beads, and swirl to dissolve the specimen. Pipet 25 mL of *Phthalic anhydride–pyridine solution* into a second, glass-stoppered, conical flask, add a few glass beads, and use as the reagent blank. (An additional 25-mL portion of pyridine may be added to both the test specimen and reagent blank, before refluxing, if necessary to ensure fluidity.) Heat both flasks, fitted with suitable reflux condensers, and allow to reflux for 1 h. Allow to cool, and pour two 10-mL portions of pyridine through each condenser. Remove the flasks from the condensers, add 10 mL of water to each, insert the stoppers, swirl, and allow to stand for 10 min. To each flask add 50.0 mL of 0.66 N sodium hydroxide and 0.5 mL of a solution (1 in 100) of phenolphthalein in pyridine. Titrate with 0.5 N sodium hydroxide VS to a light pink endpoint that persists for NLT 15 s.

Calculate the average molecular weight:

$$\text{Result} = 2000 \times W / [(V_B - V_S) \times N]$$

W = weight of the sample taken (g)

V_B = volume of 0.5 N sodium hydroxide VS consumed by the blank (mL)

V_S = volume of 0.5 N sodium hydroxide VS consumed by the residual acid in the test solution (mL)

N = actual normality of 0.5 N sodium hydroxide VS

Acceptance criteria: See the table in the *Definition*.

• WEIGHT PERCENT OXYETHYLENE

Solvent: Use deuterated water or deuteriochloroform.

NMR reference: Use sodium 2,2-dimethyl-2-silapentane-5-sulfonate (for deuterated water) or tetramethylsilane (for deuteriochloroform).

Sample solution: Dissolve 0.1–0.2 g of Poloxamer in deuterated water containing 1% of sodium 2,2-dimethyl-2-silapentane-5-sulfonate to obtain 1 mL of solution, or, if the Poloxamer does not dissolve in water, use deuteriochloroform containing 1% of tetramethylsilane as the solvent.

Instrumental conditions

(See [Nuclear Magnetic Resonance Spectroscopy \(761\)](#), [Qualitative and Quantitative NMR Analysis, Quantitative Applications, 1. Relative quantitation](#).)

Mode: Nuclear magnetic spectrometry

Sample size: 0.5–1.0 mL of the *Sample solution*

Analysis:

Sample: *Sample solution*