

Polyethylene Oxide

1 Nonproprietary Names

USPNF: Polyethylene oxide

2 Synonyms

Polyox; polyoxirane; polyoxyethylene.

3 Chemical Name and CAS Registry Number

Polyethylene oxide [25322-68-3]

4 Empirical Formula Molecular Weight

See Table I.

5 Structural Formula

The USPNF 20 describes polyethylene oxide as a nonionic homopolymer of ethylene oxide, represented by the formula $(\text{CH}_2\text{CH}_2\text{O})_n$, where n represents the average number of oxyethylene groups. It may contain up to 3% of silicon dioxide.

6 Functional Category

Mucoadhesive; tablet binder; thickening agent.

7 Applications in Pharmaceutical Formulation or Technology

Polyethylene oxide can be used as a tablet binder at concentrations of 5–85%. The higher molecular weight grades provide delayed drug release via the hydrophilic matrix approach; see Table I.

The relationship between swelling capacity and molecular weight is a good guide when selecting products for use in immediate- or sustained-release matrix formulations; see Figure 1.

Polyethylene oxide has been shown to be an excellent mucoadhesive polymer.⁽¹⁾ Low levels of polyethylene oxide are effective thickeners, although alcohol is usually added to water-based formulations to provide improved viscosity stability; see Table II. Polyethylene oxide films demonstrate good lubricity when wet. This property has been utilized in the development of coatings for medical devices. Polyethylene oxide can be radiation crosslinked in solution to produce a hydrogel that can be used in wound care applications.

8 Description

White to off-white, free-flowing powder. Slight ammoniacal odor.

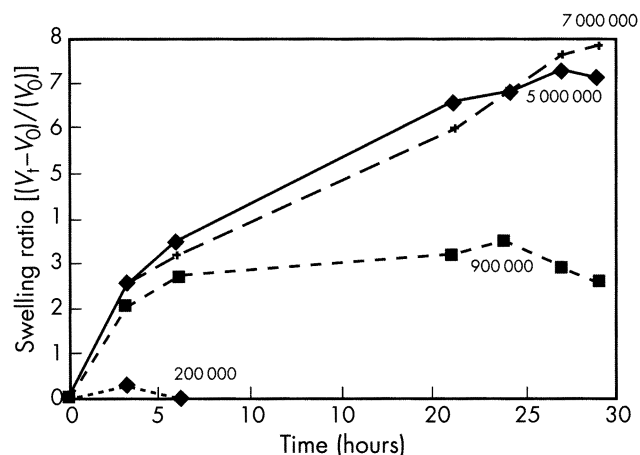


Figure 1: Swelling capacity of polyethylene oxide (Polyox WSR). Measured for four molecular weight grades; 28 mm tablets in 300 mL of water.

Table I: Number of repeat units and molecular weight as a function of polymer grade for polyethylene oxide.

Polyox grade	Approximate number of repeating units	Approximate molecular weight
WSR N-10	2 275	100 000
WSR N-80	4 500	200 000
WSR N-750	6 800	300 000
WSR N-3000	9 100	400 000
WSR 205	14 000	600 000
WSR 1105	20 000	900 000
WSR N-12K	23 000	1 000 000
WSR N-60K	45 000	2 000 000
WSR 301	90 000	4 000 000
WSR Coagulant	114 000	5 000 000
WSR 303	159 000	7 000 000

Note: molecular weight based on dilute viscosity measurements.

Table II: Polyethylene oxide viscosity at 25°C (mPa s).

Polyox grade	5% solution	2% solution	1% solution
WSR N-10	30–50	—	—
WSR N-80	55–90	—	—
WSR N-750	600–1 200	—	—
WSR N-3000	2 250–4 500	—	—
WSR 205	4 500–8 800	—	—
WSR 1105	8 800–17 600	—	—
WSR N-12K	—	400–800	—
WSR N-60K	—	2 000–4 000	—
WSR 301	—	—	1 650–5 500
WSR coagulant	—	—	5 500–7 500
WSR 303	—	—	7 500–10 000

Note: all solution concentrations are based on the water content of the hydro-alcoholic solutions.

9 Pharmacopeial Specifications

See Table III.

Table III: Pharmacopeial specifications for polyethylene oxide.

Test	USPNF 20
Identification	+
Loss on drying	≤1.0%
Silicon dioxide and nonsilicon dioxide residue on ignition	≤2.0%
Silicon dioxide	≤3.0%
Heavy metals	≤0.001%
Free ethylene oxide	≤0.001%
Organic volatile impurities	+
Viscosity	+

10 Typical Properties

Angle of repose: 34°

Density (true): 1.3 g/cm³

Melting point: 65–70°C

Moisture content: <1%

Solubility: polyethylene oxide is soluble in water and a number of common organic solvents such as acetonitrile, chloroform, and methylene chloride. It is insoluble in aliphatic hydrocarbons, ethylene glycol, and most alcohols.⁽²⁾

Viscosity (dynamic): see Table II.

11 Stability and Storage Conditions

Store in tightly sealed containers in a cool, dry place. Avoid exposure to high temperatures since this can result in reduction in viscosity.

12 Incompatibilities

Polyethylene oxide is incompatible with strong oxidizing agents.

13 Method of Manufacture

Polyethylene oxide is prepared by the polymerization of ethylene oxide using a suitable catalyst.⁽¹⁾

14 Safety

Animal studies suggest that polyethylene oxide has a low level of toxicity regardless of the route of administration. It is poorly

absorbed from the gastrointestinal tract but appears to be completely and rapidly eliminated. The resins are neither skin irritants nor sensitizers, and they do not cause eye irritation.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled.

16 Regulatory Status

Included in the FDA Inactive Ingredients Guide (sustained-release tablets).

17 Related Substances

Polyethylene glycol.

18 Comments

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19 Specific References

- 1 Bottenberg P, Cleymaet R, de Muynck C, *et al.* Development and testing of bioadhesive, fluoride-containing slow-release tablets for oral use. *J Pharm Pharmacol* 1991; 43: 457–464.
- 2 Bailey FE, Kolesky JV. *Poly(ethylene oxide)*. London: Academic Press: 1976.

20 General References

- Union Carbide Corp. Technical literature: *Polyox water soluble resin*, 1998.
- Yu DM, Amidon GL, Weiner ND, Goldberg AH. Viscoelastic properties of poly(ethylene oxide) solution. *J Pharm Sci* 1994; 83: 1443–1449.

21 Author

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22 Date of Revision

15 October 2002.