Handbook of PHARMACEUTICAL EXCIPIENTS

Third Edition

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Polyethylene Oxide

1. Nonproprietary Names

USP: 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

$(CH_2CH_2O)_n$

Polyethylene oxide is a nonionic homopolymer of ethylene oxide, where *n* represents the average number of oxyethylene groups (about 2000 to over 100 000). It may contain up to 3% of silicon dioxide.

6. Functional Category

Hydrophilic matrix formation; mucoadhesive; tablet binder; thickening agent.

7. Applications in Pharmaceutical Formulation or Technology

Polyethylene oxide can be used as a tablet binder at concentrations from 5-85%. The higher molecular weight grades provide delayed drug release via the hydrophilic matrix approach. Fig. 1 presents the relationship between swelling capacity and molecular weight which is a good guide when selecting products for use in immediate- or sustained-release matrix formulations.

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. 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. The hydrogels so produced have been used in wound-care applications.

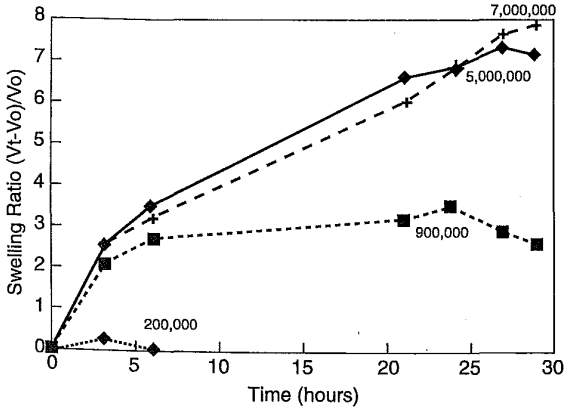

Fig. 1: Swelling capacity of polyethylene oxide (*Polyox WSR*). Measured for four molecular weight grades; 28 mm tablets in 300 mL of water.

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

Polyox grade	Approximate number of repeating units	Approximate molecular weight
WSR *N*-10	2275	100 000
WSR *N*-80	4500	200 000
WSR *N*-750	6800	300 000
WSR *N*-3000	9100	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	65-115	—	—
WSR *N*-750	600-1200	—	—
WSR N3000	2250-4500	—	—
WSR 205	4500-8800	—	—
WSR 1105	8800-17 600	—	—
WSR *N*-12K	—	400-800	—
WSR *N*-60K	—	2000-4000	—
WSR 301	—	—	1500-5500
WSR coagulant	—	—	5500-7500
WSR 303	—	—	7500-10 000

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

8. Description

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

9. Pharmacopeial Specifications

Test	USP
Identification	+
Loss on drying (105°C for 45 min)	≤ 1%
Nonsilicon dioxide loss on ignition	≤ 2%
Silicon dioxide	≤ 3%
Heavy metals	≤ 0.001%
Free ethylene oxide	≤ 10 ppm
Organic volatile impurities	+
Trichloroethylene	≤100 ppm
Viscosity	+

10. Typical Properties

Angle of repose: 34°
Density (true): 1.3 g/cc
Melting point: 65-70°C
Moisture content: < 1%. *See also* Fig. 2.

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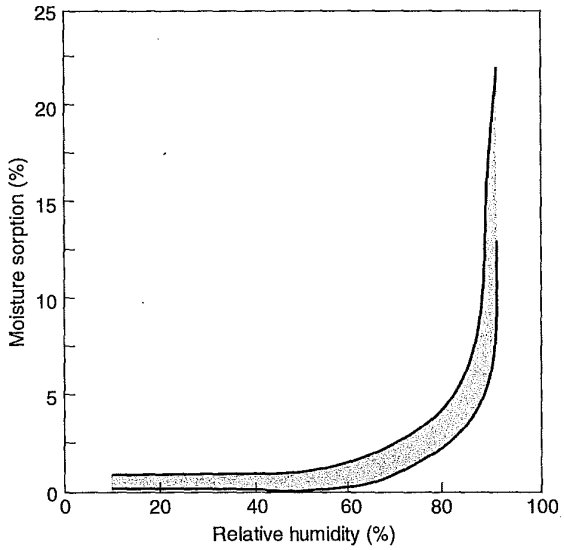

Fig. 2: Moisture sorption isotherm for polyethylene oxide (*Polyox WSR*), (Union Carbide Corp.)

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]

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 viscosity reduction.

12. Incompatibilities

Polyethylene oxide is incompatable with strong oxidizing agents.

13. Method of Manufacture

Prepared by the polymerization of ethylene oxide using a suitable catalyst.[2]

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, nor do they cause eye irritation. [6]

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. Pharmacopeias

US.

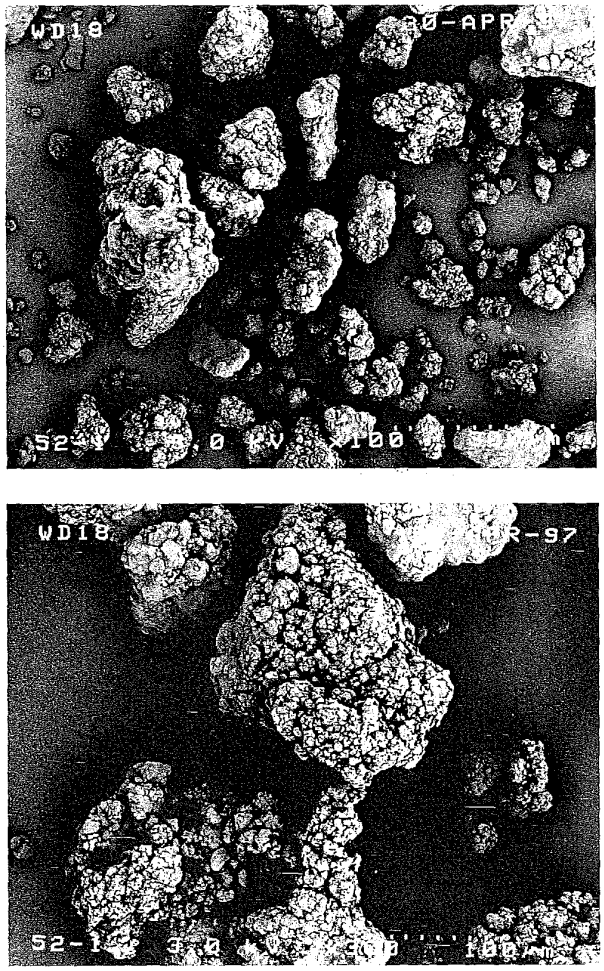

Fig. 3: SEM of polyethylene oxide (*Polyox WSR*), (Union Carbide Corp.). Magnifications at 100× (top) and 300× (bottom).

18. Related Substances

Polyethylene glycol.

19. Comments

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20. Specific References

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2. Bailey FE Jr., Kolesky JV. *Poly(ethylene oxide)*. London, Academic Press, 1976.

21. General References

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22. Author

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