

Polyvinyl Alcohol

1 Nonproprietary Names

USP: Polyvinyl alcohol

2 Synonyms

Airvol; *Elvanol*; *Gohsenol*; PVA; vinyl alcohol polymer.

3 Chemical Name and CAS Registry Number

Ethenol, homopolymer [9002-89-5]

4 Empirical Formula Molecular Weight

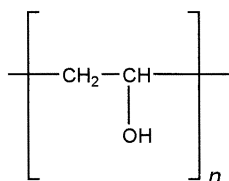
$(C_2H_4O)_n$ 20 000–200 000

Polyvinyl alcohol is a water-soluble synthetic polymer represented by the formula $(C_2H_4O)_n$. The value of n for commercially available materials lies between 500 and 5000, equivalent to a molecular weight range of approximately 20 000–200 000, see Table I.

Table I: Commercially available grades of polyvinyl alcohol.

Grade	Molecular weight
High viscosity	~ 200 000
Medium viscosity	~ 130 000
Low viscosity	~ 20 000

5 Structural Formula



6 Functional Category

Coating agent; lubricant; stabilizing agent; viscosity-increasing agent.

7 Applications in Pharmaceutical Formulation or Technology

Polyvinyl alcohol is used primarily in topical pharmaceutical and ophthalmic formulations; see Table II.⁽¹⁻³⁾ It is used as a stabilizing agent for emulsions (0.25–3.0% w/v). Polyvinyl alcohol is also used as a viscosity-increasing agent for viscous formulations such as ophthalmic products. It is used in artificial tears and contact lens solutions for lubrication purposes, in sustained-release formulations for oral administration,⁽⁴⁾ and in transdermal patches.⁽⁵⁾ Polyvinyl alcohol may be made into microspheres when mixed with a glutaraldehyde solution.⁽⁶⁾

Table II: Uses of polyvinyl alcohol.

Use	Concentration (%)
Emulsions	0.5
Ophthalmic formulations	0.25–3.00
Topical lotions	2.5

8 Description

Polyvinyl alcohol occurs as an odorless, white to cream-colored granular powder.

9 Pharmacopeial Specifications

See Table III.

Table III: Pharmacopeial specifications for polyvinyl alcohol.

Test	USP 25
Viscosity	+
pH	5.0–8.0
Loss on drying	≤ 5.0%
Residue on ignition	≤ 2.0%
Water-insoluble substances	≤ 0.1%
Degree of hydrolysis	+
Organic volatile impurities	+
Assay	85.0–115.0%

10 Typical Properties

Melting point:

228°C for fully hydrolyzed grades

180–190°C for partially hydrolyzed grades

Refractive index: $n_D^{25} = 1.49\text{--}1.53$

Solubility: soluble in water; insoluble in organic solvents.

Dissolution requires dispersion (wetting) of the solid in water at room temperature followed by heating the mixture to about 90°C for approximately 5 minutes. Mixing should be continued while the heated solution is cooled to room temperature.

Specific gravity:

1.19–1.31 for solid at 25°C

1.02 for 10% w/v aqueous solution at 25°C

Specific heat: 1.67 J/g (0.4 cal/g)

Viscosity (dynamic): see Table IV.

Table IV: Viscosity of commercial grades of polyvinyl alcohol.

Grade	Dynamic viscosity of 4% w/v aqueous solution at 20°C (mPa s)
High viscosity	40.0–65.0
Medium viscosity	21.0–33.0
Low viscosity	4.0–7.0

11 Stability and Storage Conditions

Polyvinyl alcohol is stable when stored in a tightly sealed container in a cool, dry place. Aqueous solutions are stable in corrosion-resistant sealed containers. Preservatives may be added to the solution if extended storage is required. Polyvinyl alcohol undergoes slow degradation at 100°C and rapid degradation at 200°C; it is stable on exposure to light.

12 Incompatibilities

Polyvinyl alcohol undergoes reactions typical of a compound with secondary hydroxy groups, such as esterification. It decomposes in strong acids, and softens or dissolves in weak acids and alkalis. It is incompatible at high concentration with inorganic salts, especially sulfates and phosphates; precipitation of polyvinyl alcohol 5% w/v can be caused by phosphates. Gelling of polyvinyl alcohol solution may occur if borax is present.

13 Method of Manufacture

Polyvinyl alcohol is produced through the hydrolysis of polyvinyl acetate. The repeating unit of vinyl alcohol is not used as the starting material because it cannot be obtained in the quantities and purity required for polymerization purposes. The hydrolysis proceeds rapidly in methanol, ethanol, or a mixture of alcohol and methyl acetate, using alkalis or mineral acids as catalysts.

14 Safety

Polyvinyl alcohol is generally considered a nontoxic material. It is nonirritant to the skin and eyes at concentrations up to 10%; concentrations up to 7% are used in cosmetics.

Studies in rats have shown that polyvinyl alcohol 5% w/v aqueous solution injected subcutaneously can cause anemia and infiltrate various organs and tissues.⁽⁷⁾

LD₅₀ (mouse, oral): 14.7 g/kg

LD₅₀ (rat, oral): >20 g/kg

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection and gloves are recommended. Polyvinyl alcohol dust may be an irritant on inhalation. Handle in a well-ventilated environment.

16 Regulatory Status

Included in the FDA Inactive Ingredients Guide (ophthalmic preparations and oral tablets). Included in nonparenteral medicines licensed in the UK.

17 Related Substances

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18 Comments

Various grades of polyvinyl alcohol are commercially available. The degree of polymerization and the degree of hydrolysis are the two determinants of their physical properties. Pharmaceutical grades are partially hydrolyzed materials and are named according to a coding system. The first number following a trade name refers to the degree of hydrolysis and the second set of numbers indicates the approximate viscosity (dynamic), in mPa s, of a 4% w/v aqueous solution at 20°C.

19 Specific References

- 1 Krishna N, Brow F. Polyvinyl alcohol as an ophthalmic vehicle: effect on regeneration of corneal epithelium. *Am J Ophthalmol* 1964; 57: 99–106.
- 2 Patton TF, Robinson JR. Ocular evaluation of polyvinyl alcohol vehicle in rabbits. *J Pharm Sci* 1975; 64: 1312–1316.
- 3 Anonymous. New method of ocular drug delivery launched. *Pharm J* 1993; 250: 174.
- 4 Carstensen JT, Marty JP, Puisieux F, Fessi H. Bonding mechanisms and hysteresis areas in compression cycle plots. *J Pharm Sci* 1981; 70: 222–223.
- 5 Wan LSC, Lim LY. Drug release from heat-treated polyvinyl alcohol films. *Drug Dev Ind Pharm* 1992; 18: 1895–1906.
- 6 Thanoo BC, Sunny MC, Jayakrishnan A. Controlled release of oral drugs from crosslinked polyvinyl alcohol microspheres. *J Pharm Pharmacol* 1993; 45: 16–20.
- 7 Hall CE, Hall O. Polyvinyl alcohol: relationship of physicochemical properties to hypertension and other pathophysiological sequelae. *Lab Invest* 1963; 12: 721–736.

20 General References

- Chudzikowski R. Polyvinyl alcohol. *Manuf Chem Aerosol News* 1970; 41(7): 31–37.
- Finch CA, ed. *Polyvinyl Alcohol Developments*. Chichester: Wiley, 1992.

21 Authors

SC Owen, PJ Weller.

22 Date of Revision

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