Copovidone

1 Nonproprietary Names

BP: Copovidone

PhEur: Copovidone

USP–NF: Copovidone

2 Synonyms

Acetic acid vinyl ester, polymer with 1-vinyl-2-pyrrolidinone; copolymer of 1-vinyl-2-pyrrolidone and vinyl acetate in a ratio of 3:2 by mass; copolyvidone; copovidonum; *Kollidon VA 64*; *Luviskol VA*; *Plasdone S-630*; poly(1-vinylpyrrolidone-co-vinyl acetate); polyvinylpyrrolidone-vinyl acetate copolymer; PVP/VA; PVP/VA copolymer.

3 Chemical Name and CAS Registry Number

Acetic acid ethenyl ester, polymer with 1-ethenyl-2-pyrrolidinone [25086-89-9]

4 Empirical Formula and Molecular Weight

$(C_6H_9NO)_n \cdot (C_4H_6O_2)_m$ $(111.1)_n + (86.1)_m$

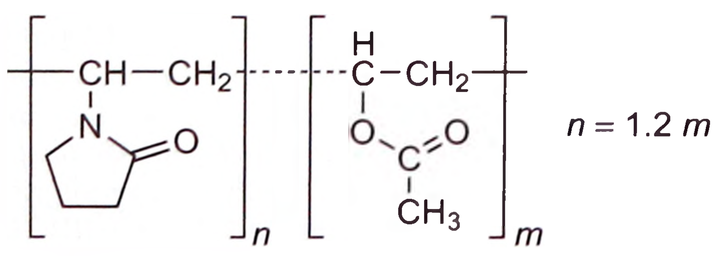
The ratio of n to m is approximately $n = 1.2m$. Molecular weights of 45 000–70 000 have been determined for *Kollidon VA 64*. The average molecular weight of copovidone is usually expressed as a *K*-value.

The *K*-value of *Kollidon VA 64* is nominally 28, with a range of 25.2–30.8. The *K*-value of *Plasdone S 630* is specified between 25.4 and 34.2. *K*-values are calculated from the kinematic viscosity of a 1% aqueous solution. Molecular weight can be calculated with the formula:

$$M = 22.22\ (K + 0.075K^{2})^{1.65}$$

The USP 40–NF 35 S1 describes copovidone as a copolymer of 1-vinyl-2–pyrrolidinone and vinyl acetate in the mass proportion of 3:2. The PhEur 9.2 describes copovidone as a copolymer of 1-ethenylpyrrolidin-2-one and ethenyl acetate in the mass proportion of 3:2.

5 Structural Formula



6 Functional Category

Film-forming agent; modified-release agent; tablet and capsule binder.

7 Applications in Pharmaceutical Formulation or Technology

Copovidone is used as a tablet binder, a film-former, and as part of the matrix material used in controlled-release formulations. In tableting, copovidone can be used as a binder for direct compression[1–4] and as a binder in wet granulation.[5,6] Copovidone is often added to coating solutions as a film-forming agent.[7] It provides good adhesion, elasticity, and hardness, and can be used as a moisture barrier.

See Table I.

Table I: Uses of copovidone.

Use	Concentration (%)
Film-forming agent	0.5–5.0[a]
Tablet binder, direct compression	2.0–5.0
Tablet binder, wet granulation	2.0–5.0

(a) This corresponds to the % w/w copovidone in the film-forming solution formulation, before spraying.

8 Description

Copovidone is a white to yellowish-white amorphous powder. It is typically spray-dried with a relatively fine particle size. It has a slight odor and a faint taste.

9 Pharmacopeial Specifications

See Table II. *See also* Section 18.

Table II: Pharmacopeial specifications for copovidone.

Test	PhEur 9.2	USP 40–NF 35 S1
Aldehydes	≤500 ppm	≤0.05%
Appearance of solution	+	+
Characters	+	—
Ethenyl acetate	35.3–42.0%	35.3–41.4%
Heavy metals	—	≤20 ppm
Hydrazine	≤1 ppm	≤1 ppm
Identification	+	+
K-value	90.0–110.0%	90.0–110.0%
Loss on drying	≤5.0%	≤5.0%
Monomers	≤0.1%	+
1-vinyl-2-pyrrolidone	—	≤0.001%
Vinyl acetate	—	≤0.001%
2-pyrrolidone	—	≤0.5%
Nitrogen content	7.0–8.0%	7.0–8.0%
Peroxides	≤400 ppm	≤0.04%
2-Pyrrolidone	≤0.5%	—
Sulfated ash	≤0.1%	—
Residue on ignition	—	≤0.1%
Viscosity, expressed as *K*-value	+	—

10 Typical Properties

Density (bulk) 0.24–0.28 g/cm^3

Density (tapped) 0.35–0.45 g/cm^3

Flash point 215°C

Flowability Relatively free-flowing powder.

Glass transition temperature 106°C for *Plasdone S-630*.[8]

Hygroscopicity At 50% relative humidity, copovidone gains less than 10% weight.

K-*value* 25.4–34.2 for *Plasdone S-630*.[8]

Melting point 140°C

Solubility Greater than 10% solubility in 1,4-butanediol, glycerol, butanol, chloroform, dichloromethane, ethanol (95%), glycerol, methanol, polyethylene glycol 400, propan-2-ol, propanol, propylene glycol, and water. Less than 1% solubility in cyclohexane, diethyl ether, liquid paraffin, and pentane.