

## 1 Nonproprietary Names

BP: Crospovidone

JP: Crospovidone

PhEur: Crospovidone

USP–NF: Crospovidone

## 2 Synonyms

*Crospopharm*; crospovidonum; crosslinked povidone; E1202; *Kollidon CL*; *Kollidon CL-M*; *Polyplasdone XL*; *Polyplasdone XL-10*; polyvinylpyrrolidone; PVPP; 1-vinyl-2-pyrrolidinone homopolymer.

## 3 Chemical Name and CAS Registry Number

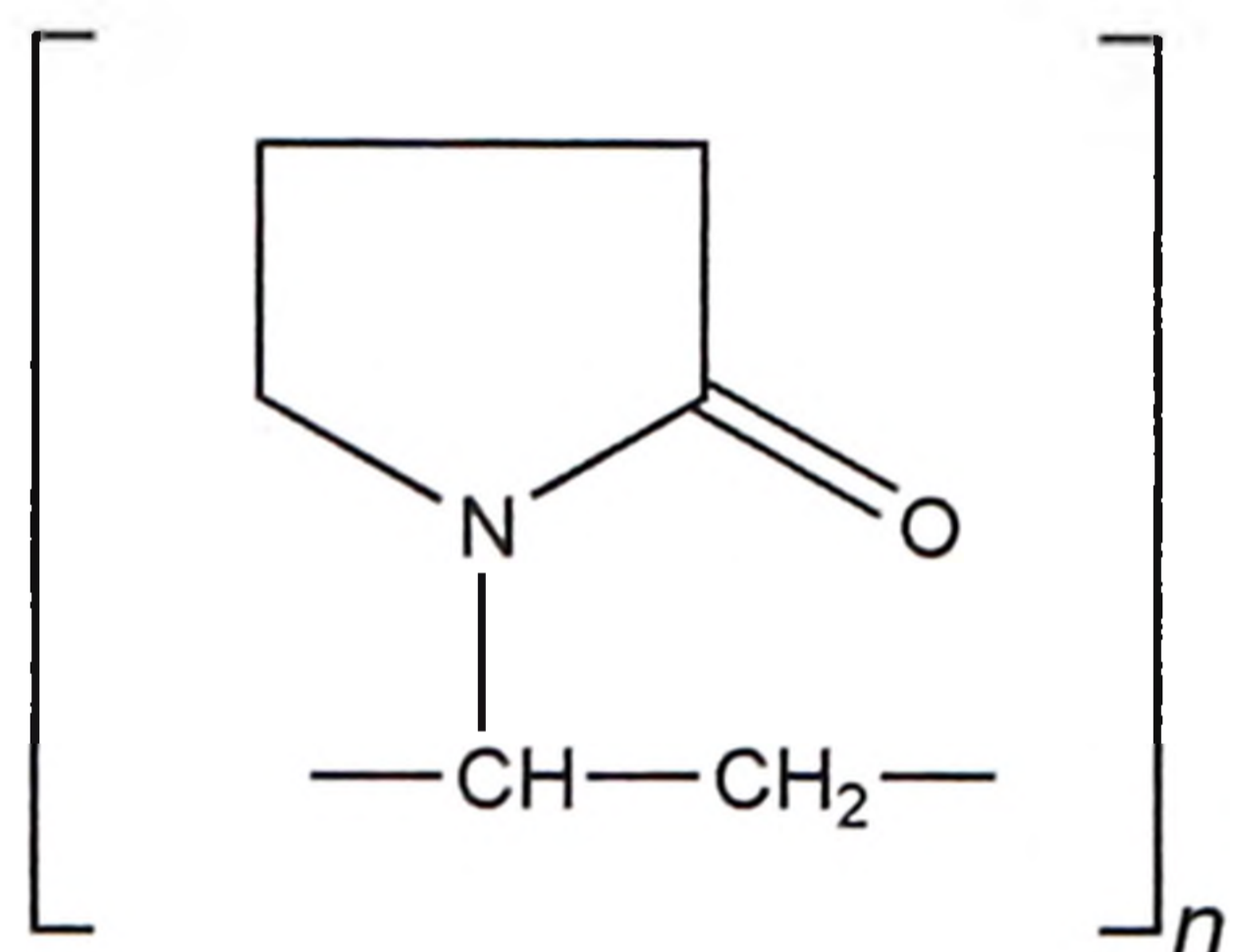
1-Ethenyl-2-pyrrolidinone homopolymer [9003-39-8]

## 4 Empirical Formula and Molecular Weight

$(C_6H_9NO)_n$  >1 000 000

The USP 40–NF 35 S1 describes crospovidone as a water-insoluble synthetic crosslinked homopolymer of *N*-vinyl-2-pyrrolidinone. An exact determination of the molecular weight has not been established because of the insolubility of the material. The structural formula in Section 5 is for the monomer used in the synthesis of crospovidone and does not show the crosslinking that occurs which makes it distinct from povidone.

## 5 Structural Formula



See also Section 4.

## 6 Functional Category

Tablet and capsule disintegrant.

## 7 Applications in Pharmaceutical Formulation or Technology

Crospovidone is a water-insoluble tablet disintegrant and dissolution agent used at 2–5% concentration in tablets prepared by direct-compression or wet- and dry-granulation methods.<sup>(1–6)</sup> It rapidly exhibits high capillary activity and pronounced hydration capacity, with little tendency to form gels. Studies suggest that the particle size of crospovidone strongly influences disintegration of analgesic tablets.<sup>(7)</sup> Larger particles provide a faster disintegration than smaller particles. Crospovidone has been suggested as an alternative to microcrystalline cellulose as an aid in pelletization.<sup>(8)</sup>

Crospovidone can also be used as a solubility enhancer. With the technique of co-evaporation, crospovidone can be used to enhance the solubility of poorly soluble drugs. The drug is adsorbed on to crospovidone in the presence of a suitable solvent and the solvent is then evaporated. This technique results in a faster dissolution rate.

Crospovidone has been studied as a superdisintegrant. The ability of the compound to swell has been examined directly using

scanning electron microscopy.<sup>(9)</sup> The impact of crospovidone on percolation<sup>(10)</sup> and on dissolution of poorly soluble drugs in tablets<sup>(11)</sup> has also been investigated. It has also been evaluated for use in fast disintegrating tablets,<sup>(12)</sup> and has been shown to be effective with highly hygroscopic drugs.<sup>(13)</sup> It continues to be examined for its uses in a number of tablet formulations; specifically in the development of floating tablets,<sup>(14)</sup> rapidly dissolving tablets<sup>(15)</sup> and controlled-release formulations,<sup>(16)</sup> where crospovidone acted as a swelling agent, and a buoyancy, disintegrant and compression aid.

## 8 Description

Crospovidone is a white to creamy-white, finely divided, free-flowing, practically tasteless, odorless or nearly odorless, hygroscopic powder.

## 9 Pharmacopeial Specifications

The pharmacopeial specifications for crospovidone have undergone harmonization of many attributes for PhEur, and USP–NF.

See Table I. See also Section 18.

**Table I:** Pharmacopeial specifications for crospovidone.

Test	JP XVII	PhEur 9.2	USP 40–NF 35 S1
Identification <sup>(a)</sup>	+	+	+
Characters <sup>(a)</sup>	–	+	–
Residue on ignition	≤0.1%	≤0.1%	≤0.1%
Water-soluble substances	+	≤1.5%	≤1.5%
Peroxides			
Type A	≤400 ppm	≤400 ppm	≤400 ppm
Type B	≤1000 ppm	≤1000 ppm	≤1000 ppm
Heavy metals <sup>(a)</sup>	≤10 ppm	–	≤10 ppm
Vinylpyrrolidinone	≤10 ppm	≤10 ppm	≤10 ppm
Loss on drying	≤5.0%	≤5.0%	≤5.0%
Nitrogen content (anhydrous basis)	11.0–12.8%	11.0–12.8%	11.0–12.8%

(a) These tests have not been fully harmonized at the time of publication.

## 10 Typical Properties

*Acidity/alkalinity* pH = 5.0–8.0 (1% w/v aqueous slurry)

*Density* 1.22 g/cm<sup>3</sup>

*Density (bulk)* see Table II.

*Density (tapped)* see Table II.

**Table II:** Density values of commercial grades of crospovidone.

Commercial grade	Density (bulk) (g/cm <sup>3</sup> )	Density (tapped) (g/cm <sup>3</sup> )
<i>Kollidon CL</i>	0.3–0.4	0.4–0.5
<i>Kollidon CL-M</i>	0.15–0.25	0.3–0.5
<i>Polyplasdone XL</i>	0.213	0.273
<i>Polyplasdone XL-10</i>	0.323	0.461

*Moisture content* Maximum moisture sorption is approximately 60%.

*Particle size distribution* Less than 400 μm for *Polyplasdone XL*; less than 74 μm for *Polyplasdone XL-10*. Approximately 50% greater than 50 μm and maximum of 3% greater than 250 μm in